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Presidential Documents

Title 3—

The President

Executive Order 13735 of August 12, 2016

Providing an Order of Succession Within the Department of the Treasury

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the "Act"), it is hereby ordered that:

Section 1. Subject to the provisions of section 3 of this Executive Order, the officers named in section 2, in the order listed, shall act as and perform the functions and duties of the office of Secretary of the Treasury (Secretary) during any period when both the Secretary and the Deputy Secretary of the Treasury have died, resigned, or are otherwise unable to perform the functions and duties of the office of Secretary.

Sec. 2. *Order of Succession.* (a) Under Secretaries of the Treasury, in the order in which they shall have taken the oath of office as such officers;

(b) General Counsel of the Department of the Treasury;

(c) Deputy Under Secretaries of the Treasury and those Assistant Secretaries of the Treasury appointed by the President by and with the consent of the Senate, in the order in which they shall have taken the oath of office as such officers; and

(d) the following officers of the Department of the Treasury, in the order listed:

(i) Chief of Staff;

(ii) Assistant Secretary for Management;

(iii) Fiscal Assistant Secretary;

(iv) Commissioner of Internal Revenue, Internal Revenue Service;

(v) Commissioner, Bureau of the Fiscal Service;

(vi) Deputy Commissioner, Fiscal Accounting and Shared Services, Bureau of the Fiscal Service; and

(vii) Commissioner, Wage and Investment Division, Internal Revenue Service.

Sec. 3. *Exceptions.* (a) No individual who is serving in an office listed in section 2(a)–(d) in an acting capacity shall, by virtue of so serving, act as Secretary pursuant to this Executive Order.

(b) Notwithstanding the provisions of this Executive Order, the President retains discretion, to the extent permitted by the Act, to depart from this Executive Order in designating an acting Secretary.

(c) No individual listed in section 2(a)–(d) shall act as Secretary unless that individual is otherwise eligible to serve under the Act.

Sec. 4. *Revocation.* Executive Order 13246 of December 18, 2001, and the Presidential Memorandum of March 19, 2002 ("Designation of Officers of the Department of the Treasury"), are hereby revoked.

Sec. 5. *Judicial Review*. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
August 12, 2016.

[FR Doc. 2016–19723
Filed 8–16–16; 8:45 am]
Billing code 3295–F6–P

Presidential Documents

Executive Order 13736 of August 12, 2016

Providing an Order of Succession Within the Department of Veterans Affairs

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the "Act"), it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this order and to the limitations set forth in the Act, the following officials of the Department of Veterans Affairs, in the order listed, shall act as Secretary of Veterans Affairs (Secretary) and perform the functions and duties of the office of the Secretary during any period in which both the Secretary and the Deputy Secretary of Veterans Affairs have died, resigned, or otherwise become unable to perform the functions and duties of the office of Secretary:

(a) Under Secretary for Health;

(b) Under Secretary for Benefits;

(c) Under Secretary for Memorial Affairs;

(d) Chief of Staff;

(e) General Counsel and Assistant Secretaries, with precedence among them in the order, by date, of their appointments and, if on the same date, in the order in which they have taken the oath of office;

(f) Chairman, Board of Veterans' Appeals;

(g) Network Director, Veterans Integrated Service Network 8;

(h) Network Director, Veterans Integrated Service Network 7;

(i) Director, Southern Area, Veterans Benefits Administration; and

(j) Network Director, Veterans Integrated Service Network 19.

Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1(a)–(j) of this order in an acting capacity shall, by virtue of so serving, act as Secretary pursuant to this order.

(b) No individual who is serving in an office listed in section 1(a)–(j) of this order shall act as Secretary unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this order, the President retains discretion, to the extent permitted by law, to depart from this order in designating an acting Secretary.

Sec. 3. *Revocations.* (a) Executive Order 13247 of December 18, 2001, is hereby revoked;

(b) Section 4(g) of Executive Order 13261 of March 19, 2002, is hereby revoked;

(c) Presidential Memorandum of March 19, 2002 (Designation of Officers of the Department of Veterans Affairs), is hereby revoked; and

(d) Presidential Memorandum of February 12, 2003 (Designation of Officers of the Department of Veterans Affairs to Act as Secretary of Veterans Affairs), is hereby revoked.

Sec. 4. *Judicial Review.* This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
August 12, 2016.

[FR Doc. 2016–19724
Filed 8–16–16; 8:45 am]
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Presidential Documents

Executive Order 13737 of August 12, 2016

Providing an Order of Succession Within the Environmental Protection Agency

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the "Act"), it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this order, and to the limitations set forth in the Act, the following officials of the Environmental Protection Agency, in the order listed, shall act as and perform the functions and duties of the office of the Administrator of the Environmental Protection Agency (Administrator) during any period in which the Administrator and the Deputy Administrator of the Environmental Protection Agency have died, resigned, or become otherwise unable to perform the functions and duties of the office of Administrator:

(a) General Counsel;

(b) Assistant Administrator for the Office of Solid Waste;

(c) Assistant Administrator for Toxic Substances (also known as the Assistant Administrator for the Office of Chemical Safety and Pollution Prevention);

(d) Assistant Administrator for the Office of Air and Radiation;

(e) Assistant Administrator for the Office of Water;

(f) Assistant Administrator for the Office of Enforcement and Compliance Assurance;

(g) Chief Financial Officer;

(h) Assistant Administrator for the Office of Research and Development;

(i) Assistant Administrator for the Office of International and Tribal Affairs;

(j) Assistant Administrator for the Office of Administration and Resources Management;

(k) Assistant Administrator for the Office of Environmental Information;

(l) Regional Administrator, Region 7;

(m) Principal Deputy General Counsel;

(n) Principal Deputy Assistant Administrator for the Office of Enforcement and Compliance Assurance;

(o) Deputy Regional Administrator, Region 2; and

(p) Deputy Regional Administrator, Region 5.

Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1(a)–(p) of this order in an acting capacity shall, by virtue of so serving, act as Administrator pursuant to this order.

(b) No individual listed in section 1(a)–(p) of this order shall act as Administrator unless that individual is otherwise eligible to so serve under the Federal Vacancies Reform Act of 1998, as amended.

(c) Notwithstanding the provisions of this order, the President retains discretion, to the extent permitted by law, to depart from this order in designating an acting Administrator.

Sec. 3. *Revocation*. Executive Order 13614 of May 21, 2012 (Providing an Order of Succession Within the Environmental Protection Agency), is hereby revoked.

Sec. 4. *Judicial Review*. This order is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

THE WHITE HOUSE,
August 12, 2016.

[FR Doc. 2016–19725
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Presidential Documents

Memorandum of August 12, 2016

Designation of Officers of the Office of Personnel Management To Act as Director of the Office of Personnel Management

Memorandum for the Director of the Office of Personnel Management

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the "Act"), it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this memorandum and to the limitations set forth in the Act, the following officials of the Office of Personnel Management (OPM), in the order listed, shall act as and perform the functions and duties of the Director of OPM (Director) during any period in which both the Director and the Deputy Director of OPM have died, resigned, or otherwise become unable to perform the functions and duties of the office of Director:

(a) General Counsel;

(b) Chief of Staff;

(c) Chief Management Officer;

(d) Chief Financial Officer;

(e) Associate Director, Employee Services;

(f) Associate Director, Retirement Services; and

(g) Other Associate Directors in the order in which they have been appointed as such.

Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1(a)–(g) in an acting capacity, by virtue of so serving, shall act as Director pursuant to this memorandum.

(b) No individual listed in section 1(a)–(g) shall act as Director unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this memorandum, the President retains discretion, to the extent permitted by law, to depart from this memorandum in designating an acting Director.

Sec. 3. *Revocation.* Presidential Memorandum of May 21, 2012 (Designation of Officers of the Office of Personnel Management to Act as Director of the Office of Personnel Management), is hereby revoked.

Sec. 4. *General Provisions.* (a) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(b) You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, August 12, 2016

[FR Doc. 2016–19726
Filed 8–16–16; 8:45 am]
Billing code 6325–01–P

Presidential Documents

Memorandum of August 12, 2016

Providing an Order of Succession Within the National Endowment for the Humanities

Memorandum for the Chairperson of the National Endowment for the Humanities

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the Federal Vacancies Reform Act of 1998, as amended, 5 U.S.C. 3345 *et seq.* (the "Act"), it is hereby ordered that:

Section 1. *Order of Succession.* Subject to the provisions of section 2 of this memorandum, and to the limitations set forth in the Act, the following officials of the National Endowment for the Humanities, in the order listed, shall act as the Chairperson of the National Endowment for the Humanities (Chairperson) and perform the functions and duties of the office of the Chairperson during any period in which the Chairperson has died, resigned, or otherwise become unable to perform the functions and duties of the office of Chairperson:

(a) Deputy Chairman;

(b) Chief of Staff;

(c) Assistant Chairman for Planning and Operations; and

(d) Assistant Chairman for Programs.

Sec. 2. *Exceptions.* (a) No individual who is serving in an office listed in section 1(a)–(d) of this memorandum in an acting capacity shall, by virtue of so serving, act as Chairperson pursuant to this memorandum.

(b) No individual who is serving in an office listed in section 1(a)–(d) of this memorandum shall act as Chairperson unless that individual is otherwise eligible to so serve under the Act.

(c) Notwithstanding the provisions of this memorandum, the President retains discretion, to the extent permitted by law, to depart from this memorandum in designating an acting Chairperson.

Sec. 3. *General Provisions.* (a) This memorandum is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity by any party against the United States, its departments, agencies, or entities, its officers, employees, or agents, or any other person.

(b) You are authorized and directed to publish this memorandum in the *Federal Register*.

THE WHITE HOUSE,
Washington, August 12, 2016

[FR Doc. 2016–19728
Filed 8–16–16; 8:45 am]
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Rules and Regulations

Federal Register
Vol. 81, No. 159
Wednesday, August 17, 2016

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 981

[Doc. No. AMS–SC–16–0047; SC16–981–3 IR]

Almonds Grown in California; Change in Quality Control Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: This rule implements a recommendation from the Almond Board of California (Board) to change the quality control requirements currently prescribed under the California almond marketing order (order). The order regulates the handling of almonds grown in California. The Board locally administers the order and is comprised of growers and handlers operating within California. This rule relaxes incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation decreases California almond handlers' disposition obligation. This change also allows handlers more flexibility in their operations while continuing to maintain quality control and ensuring compliance with the order's requirements.

DATES: Effective August 18, 2016; comments received by October 17, 2016 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* All comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be made available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Andrea Ricci, Marketing Specialist or Jeffrey Smutny, Regional Director, California Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (559) 487–5901, Fax: (559) 487–5906, or Email: *Andrea.Ricci@ams.usda.gov* or *Jeffrey.Smutny@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order No. 981, as amended (7 CFR part 981), regulating the handling of almonds grown in California, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this rule in conformance with Executive Orders 12866, 13563, and 13175.

This rule has been reviewed under Executive Order 12988, Civil Justice Reform. This rule is not intended to have retroactive effect.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This rule implements a recommendation from the Almond Board of California (Board) to change the quality control requirements currently prescribed under the order. This rule relaxes incoming quality requirements by increasing the inedible kernel tolerance from 0.50 percent to 2 percent. This relaxation would decrease California almond handler's disposition obligation. This will allow handlers more flexibility in their operations while continuing to maintain quality control. In addition, this change will ensure that the reporting and outgoing quality requirements of the order are met. The Board unanimously recommended this change at its April 12, 2016, meeting.

Section 981.42 of the almond marketing order provides authority for quality control regulations. Paragraph (a) of that section requires that almonds must be inspected prior to processing to determine the percentage of inedible kernels in each lot. Inedible kernels are defined in § 981.408. The Board, with the approval of the Secretary, may change the approved percentage of inedible kernels for any crop year. Inedible kernels in excess of the approved percentage of the kernel weight constitute the handlers' inedible disposition weight obligation. Handlers must satisfy their obligation by disposing of inedible kernels in Board-accepted, non-human outlets such as animal feed or oil.

Section 981.442(a)(4)(i) of the order's rules and regulations currently specifies that the weight of inedible kernels in excess of 0.50 percent of kernel weight shall constitute the handler's disposition obligation. Pursuant to § 981.442(a)(5), handlers must meet their disposition obligation by delivering inedible kernels to crushers, feed manufacturers, feeders, or dealers in nut wastes on record with the Board as accepted users.

In the past several years, the total inedible kernel percentages have been trending lower. This is partially due to good agricultural practices used by growers and better technologies in handler facilities. At the same time, the market value of almonds has increased significantly. As a result, some Board-accepted outlets have started to clean and repurpose the disposition obligation delivered by handlers. After the inedible disposition is delivered to Board-accepted outlets, these accepted outlets provide to the Board a record of disposition receipt, which indicates what was received by the accepted outlet from handlers and how the accepted outlet disposed of the inedible disposition. However, such record of disposition receipt does not indicate whether the almonds have been pasteurized or treated for human consumption. Thus the action of repurposing has led to concern that the order's outgoing quality requirements are not being met.

By increasing the inedible kernel tolerance, handlers' disposition obligation will decrease or become zero, therefore reducing the quantity of product delivered to those specified outlets. This action will also provide handlers with more control over low quality product allowing one handler the flexibility to transfer the larger portion of low quality product to another handler for further cleaning. This action will require completion of an interhandler transfer form and help with traceability of low quality product. It also will help ensure that any product destined for human consumption was in compliance with the pertinent regulations under the order.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 6,800 almond growers in the production area and approximately 100 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts of less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

The National Agricultural Statistics Service (NASS) reported in its 2012 Agricultural Census that there were 6,841 almond farms in the production area (California), of which 6,204 had bearing acres. The following computation provides an estimate of the proportion of producers (farms) and agricultural service firms (handlers) that would be considered small under the SBA definitions.

The NASS Census data indicates that out of the 6,204 California farms with bearing acres of almonds, 4,471 (72 percent) have fewer than 100 bearing acres.

For the almond industry's most recently reported crop year (2014), NASS reported an average yield of 2,150 pounds per acre, and a season average grower price of $3.19 per pound. A 100-acre farm with an average yield of 2,150 pounds per acre would produce about 215,000 pounds of almonds. At $3.19 per pound, that farm's production would be valued at $685,850. Since Census of Agriculture indicates that the majority of California's almond farms are smaller than 100 acres, it could be concluded that the majority of growers had annual receipts from the sale of almonds in 2014–15 of less than $685,850, which is below the SBA threshold of $750,000. Thus, over 70 percent of California's almond growers would be considered small growers according to SBA's definition.

According to information supplied by the Board, approximately 30 percent of California's almond handlers shipped almonds valued under $7,500,000 during the 2014–15 crop year, and would, therefore, be considered small handlers according to the SBA definition.

This rule revises § 981.442(a)(4)(i) of the order's administrative rules and regulations regarding inedible kernel tolerance. Specifically, this action increases the inedible kernel tolerance from 0.50 percent to 2 percent, effectively decreasing handler's disposition obligation. Authority for this action is provided in § 981.42(a) of the order.

Regarding the impact of this action on affected entities, increasing the inedible kernel tolerance reduces disposition obligation on handlers and provides handlers with more flexibility and control over the poor quality product. This rule is not expected to change handler inspection costs, as handlers currently are required to have all lots inspected to determine the percentage of inedible kernels.

The Board considered alternatives to this action. It formed a taskforce to examine the current inedible program and investigate alternatives. The taskforce reviewed the program and recent data, surveyed handlers, and reported their findings to the Almond Quality and Food Safety Committee (Committee). Recent data showed that the overall inedible kernel percentages have been trending lower, regardless of crop size. Surveyed handlers who did not agree with the change raised the concern that increasing the tolerance could result in more poor quality almonds entering the market. The Committee discussed the concerns raised and concluded that changing the tolerance would give handlers more flexibility in maintaining quality. After discussing the taskforce's findings, the Committee unanimously recommended this increase in inedible tolerance to the Board.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0178 (Vegetable and Specialty Crops.) No changes are necessary in those requirements as a result of this action. Should any changes become necessary, they would be submitted to OMB for approval.

This rule will not impose any additional reporting or recordkeeping requirements on either small or large almond handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

In addition, USDA has not identified any relevant Federal rules that duplicate, overlap or conflict with this rule.

Further, the Board's meeting was widely publicized throughout the almond industry and all interested persons were invited to attend the meeting and participate in Board deliberations. Like all Board meetings, the April 12, 2016, meeting was a public meeting and all entities, both large and small, were able to express their views on this issue.

Also, the Board has a number of appointed committees to review certain issues and make recommendations to the Board. The Board's Almond Quality and Food Safety Committee met on April 5, 2016, and discussed this issue in detail. That meeting was also a public meeting, and both large and small entities were able to participate and express their views. Finally, interested persons are invited to submit comments on this interim rule, including the regulatory and informational impacts of this action on small businesses.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

This rule invites comments on a change to the quality control requirements currently prescribed under the order. Any comments timely received will be considered prior to finalization of this rule.

After consideration of all relevant material presented, including the Board's recommendation, and other information, it is found that this interim rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this rule until 30 days after publication in the **Federal Register** because: (1) This rule relaxes the current rules and regulations; (2) this rule should be in place in time for the beginning of the crop year on August 1; (3) the Board unanimously recommended these changes at a public meeting and interested parties had an opportunity to provide input; and (4) this rule provides a 60-day comment period and any comments timely received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Part 981

Almonds, Marketing agreements, Nuts, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 981 is amended as follows:

PART 981—ALMONDS GROWN IN CALIFORNIA

■ 1. The authority citation for 7 CFR part 981 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 981.442(a)(4)(i) is revised to read as follows:

§ 981.442 Quality Control.

(a) * * *

(4) *Disposition obligation.* (i) Beginning August 1, 2016, the weight of inedible kernels in excess of 2 percent of kernel weight reported to the Board of any variety received by a handler shall constitute that handler's disposition obligation. For any almonds sold inshell, the weight may be reported to the Board and the disposition obligation for that variety reduced proportionately.

* * * * *

Dated: August 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–19625 Filed 8–16–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF ENERGY

10 CFR Part 430

[Docket No. EERE–2013–BT–TP–0050]

RIN 1904–AD10

Energy Conservation Program: Test Procedures for Ceiling Fans; Correction

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Final rule; technical correction.

SUMMARY: On July 25, 2016, the U.S. Department of Energy published a final rule amending test procedures for ceiling fans. 81 FR 48619. This correction addresses an amendatory term error in that final rule.

DATES: The correction is effective August 24, 2016.

FOR FURTHER INFORMATION CONTACT:

Ms. Lucy deButts, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 287–1604. Email: *ceiling_fans@ee.doe.gov.*

Ms. Elizabeth Kohl, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC, 20585–0121. Telephone: (202) 586–7796. Email: *elizabeth.kohl@hq.doe.gov.*

SUPPLEMENTARY INFORMATION: The U.S. Department of Energy (DOE) published a final rule in the **Federal Register** on July 25, 2016 ("the July 2016 final rule") amending test procedures for ceiling fans. 81 FR 48619. This correction addresses an amendatory term error in that final rule. Specifically, the instructions amending appendix U to subpart B of part 430—Uniform Test Method for Measuring the Energy Consumption of Ceiling Fans, stated that appendix U is "added". Since 10 CFR part 430 already includes appendix U, the instruction amending appendix U should use the amendatory term "revised." This document corrects appendix U instructions to use the correct amendatory term "revised."

Correction

■ In FR Doc. 2016–17139, appearing on page 48640, in the issue of Monday, July 25, 2016, amendatory instruction 7. is corrected to read as follows:

Appendix U to Subpart B of Part 430 [Corrected]

■ 7. Appendix U to subpart B of part 430 is revised to read as follows:

* * * * *

Issued in Washington, DC on August 11, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

[FR Doc. 2016–19621 Filed 8–16–16; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF COMMERCE

Bureau of Industry and Security

15 CFR Part 758

[Docket No. 150107020–6464–02]

RIN 0694–AG47

Revisions to the Export Administration Regulations (EAR): Harmonization of the Destination Control Statements

AGENCY: Bureau of Industry and Security, Department of Commerce.

ACTION: Final rule.

SUMMARY: This final rule implements changes that were proposed on May 22, 2015, in a proposed rule entitled *Revisions to the Export Administration Regulations (EAR): Harmonization of the Destination Control Statements.* This final rule revises the destination control statement in § 758.6 of the

Export Administration Regulations (EAR) to harmonize the statement required for the export of items subject to the EAR with the destination control statement in § 123.9(b)(1) of the International Traffic in Arms Regulations (ITAR).

DATES: This rule is effective November 15, 2016.

ADDRESSES: Commerce's full retrospective regulatory review plan can be accessed at: *http://open.commerce.gov/news/2015/03/20/commerce-plan-retrospective-analysis-existing-rules-0.*

FOR FURTHER INFORMATION CONTACT: For questions about this rule, contact Timothy Mooney, Regulatory Policy Division, Office of Exporter Services, Bureau of Industry and Security, at 202–482–2440 or email: *timothy.mooney@bis.doc.gov.*

SUPPLEMENTARY INFORMATION: This final rule is published in conjunction with the publication elsewhere in this issue of the **Federal Register** of a Department of State, Directorate of Defense Trade Controls final rule revising § 123.9(b)(1) of the ITAR. Both final rules are part of the President's Export Control Reform Initiative. This final rule is also part of Commerce's retrospective regulatory review plan under Executive Order (E.O.) 13563 (see below for availability of the plan).

Background

Prior to the effective date of this final rule, the EAR required exporters to include a destination control statement ("DCS"), specified in § 758.6 (Destination control statement and other information furnished to consignees) of the EAR, on certain export control documents that accompanied a shipment for most exports. The purpose of the DCS was to alert parties outside the United States that receive the item that the item was subject to the EAR, the item was exported in accordance with the EAR, and that diversion contrary to U.S. law was prohibited.

Prior to the effective date of the State final rule, the ITAR, under § 123.9(b)(1), included the same type of DCS requirement, but with slightly different text than that which was required by the EAR. The purpose of the DCS requirements was the same under both sets of export control regulations. As a general principle of the Export Control Reform (ECR) effort, wherever the ITAR and EAR have provisions that are intended to achieve the same purpose, the U.S. Government will harmonize the corresponding provisions.

As was stated in the Commerce and State proposed rules, the DCS under the ITAR and the EAR were an example of requirements that could and should be harmonized to reduce the burden on exporters, improve compliance, and ensure that the regulations are achieving their intended purpose for use under the U.S. export control system, specifically under the transactions "subject to the ITAR" and "subject to the EAR." This final rule is revising § 758.6 of the EAR to harmonize the DCS requirement text with § 123.9(b)(1) of the ITAR.

Under the existing provisions, both regulations have a mandatory DCS that must be on the export control documents for shipments that include items subject to those regulations. This had caused confusion to exporters as to which statement to include on such mixed shipments, or whether to include both. The harmonization of these statements in this final rule will ease the regulatory burden on exporters, which, based on the public comments described below and the additional changes made in the Commerce and State final rules in response to those comments, will further the objectives of the DCS requirements.

The change is also being made in this final rule to harmonize the two sets of regulations, the EAR and the ITAR, per the President's instructions. While the creation of a single export control list and licensing agency would require legislation, the President has directed BIS and the Directorate of Defense Trade Controls at the Department of State to undertake all available actions to prepare for consolidation as a single agency with a single set of regulations. Harmonization, to the extent possible, of the existing export control regulations is one important step for preparing both regulators and the regulated public for the work that will be needed to create such regulations.

Public Comments and BIS Responses

The public comment period on the May 22, 2015, proposed rule (80 FR 29551) closed on July 6, 2015. BIS received 17 public comments on the EAR proposed rule. Most of the commenters sent the same comments to Commerce and State expressing their support or concerns regarding the DCS related provisions included in the Commerce and State proposed rules. There were slightly different points of emphasis that were specific to the Commerce and State proposed rules, but substantively the comments were not different in any meaningful way in what the commenters thought needed to be changed in order to achieve the stated objectives in the Commerce and State proposed rules. The following describes the public comments and BIS's responses. After making changes to what was proposed to address the public comments and better achieve the stated objectives, Commerce and State are concurrently publishing final rules to harmonize the DCS provisions under the EAR and ITAR. Commerce and State agree with the public commenters that, as proposed, the harmonization did not go far enough and in order to have true harmonization and achieve the stated objectives that additional harmonization was needed. In addition, certain clarifications and refinements of what was originally proposed were needed in order to clarify and alleviate perceived concerns, in particular for exporters of non-600 series and non-9x515 items under the EAR. Where BIS has made regulatory changes to address the public comments, a description of those changes is included beneath the respective public comments and BIS responses. BIS has made these regulatory changes to § 758.6 to address the public comments and to better achieve the stated objectives of the rule. The public comment process was helpful in identifying areas where changes needed to be made to fully achieve the intended objectives for the DCS for use under the EAR and the ITAR. The following are the BIS responses to the comments:

Supportive

Comment 1: Several commenters were supportive of the plan to harmonize the DCS and noted the proposed changes: (1) Will minimize confusion as to which DCS must be used depending on the jurisdiction of item, (2) will exclude EAR and ITAR-specific text—meaning it can be used under both sets of regulations; and (3) will help to achieve the stated intent of the ECR initiative principles, which includes elimination of unnecessary export compliance burdens.

BIS response: BIS agrees. These commenters support that the key objectives of the rule have been met.

Not Supportive

Comment 2: Expresses significant concern and requests clarification, but also wishes to note that in general supports BIS's efforts to harmonize the DCS and thereby reduce the burden on exporters, promote consistency, improve compliance, and ensure the regulations are achieving the intended purpose for use under the U.S. export control system.

BIS response: BIS was encouraged that even for the commenters that raised significant concerns about certain aspects of the proposed rule that most of these same commenters still supported the general objective of harmonization of the DCS under the EAR and ITAR. Once BIS made changes to address their concerns on certain aspects of the proposed rule, these commenters would likely fully support the final rule because they viewed harmonization of the DCS as a positive step and their support was only qualified because of certain aspects of the proposed rule, which BIS has addressed in this final rule, as described further below.

Comment 3: Proposed DCS language focuses too much on harmonizing the EAR's language with the ITAR's DCS. While this is a potentially positive outcome for companies involved in defense trade, this approach does not take into account non-military exporters and the nature of commercial transactions.

BIS response: BIS is addressing these concerns by defining some of the key terms used in the DCS as they are interpreted in the EAR context, including providing some specific application examples in this final rule. These changes will address the various concerns in this area that were raised by various commenters as it related to NLR shipments or multi-step transactions that consist of discrete controlled events (*e.g.*, "exported" to a distributor as one discrete controlled event, and then a subsequent "reexport" as another discrete controlled event under the EAR). The proposed rule did not change any of the obligations of the parties to the transaction in these situations under the EAR, but the text of the DCS made some people worry how the DCS text would be applied in the EAR context, which BIS is addressing with some clarifying examples and defining how some of these key terms used in the DCS text is interpreted in the EAR context in this final rule. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, addition of Note 1 to paragraph (a). This final rule adds Note 1 to paragraph (a) to clarify the term "authorized" includes exports, reexports and transfers (in-country) designated under No License Required (NLR), which was explained in the preamble of the proposed rule, but one commenter requested this be added to the regulatory text. In addition, several other commenters did not understand that in the context of paragraph (a) the term "authorized" also includes NLR. BIS agrees that specifying this for purposes of this section is helpful and therefore this final rule is adding the new Note to paragraph (a). Because NLR is specific to the EAR, no changes are being made to the ITAR's DCS to address this comment. Similarly, the Note 2 to paragraph (a) described in the next paragraph is specific to the application under the EAR, so no changes are being made in the ITAR rule to add similar clarifying notes.

In § 758.6, addition of Note 2 to paragraph (a). This final rule adds Note 2 to paragraph (a) to specify the phrase 'country of ultimate destination' means the country specified on the commercial invoice where the ultimate consignee or end user will receive the items as an "export." The term "export" is a long established and well understood term under the EAR, so the use of this term in Note 2 will assist exporters' understanding of the use of the phrase 'country of ultimate destination'' in the DCS requirements in the context of the EAR. This final rule provides two examples here for using Note 2 to paragraph (a) to determine the 'country of ultimate destination.' Example 1: If the exporter is "exporting" directly to an end user, such as generally permitted pursuant to § 750.7(c)(1)(ix) under a BIS license, the commercial invoice must be provided to the end user, which in this scenario is in the 'country of ultimate destination.' Example 2: If the exporter is exporting to an ultimate consignee, such as a distributor, the 'country of ultimate destination' in these exports is the destination of the ultimate consignee. This was a major concern that several commenters raised on the proposed rule, in particular for exporters of non-600 series and non-9x515 items. The addition of Note 2 addresses those comments and will improve understanding of the DCS in the EAR.

Comment 4: We applaud the U.S. government's attempt to simplify and improve the export clearance process (export clearance process refers to the regulatory requirements that need to be followed under the EAR and ITAR at the time of export to clear the final steps in exporting an item, *e.g.*, filing Electronic Export Information (EEI)); however, you are proposing changes that will require every organization that exports products from the U.S. to revise their systems, when the need is appropriate only for ITAR or EAR license-required 9x515 and 600-series shipments. The proposed changes will impose a regulatory burden on all U.S. exporters without any apparent enhancement to compliance; and increase the uncertainty among foreign recipients.

BIS response: BIS does not agree. There are benefits that this harmonization will bring for exporters of "600 series" (what the commenters refers to as defense exporters) and 9x515 items. However, all exporters will benefit from a reduction in the number of documents that the DCS needs to be placed on under the EAR and the ITAR. In addition, as was noted in the support for not requiring the DCS on transportation documents (such as the air waybill), the existing DCS provisions imposed a requirement on many transportation related documents that in many cases were not reaching the consignees for which the statement was intended. The EAR were imposing a requirement to place the DCS on transportation documents that, although important to a transaction, do not in most cases reach the ultimate consignee or end-user(s). Requirements that do not achieve their objectives should be revised or removed. The objectives of the DCS are to ensure that the statement reaches the ultimate destination and ultimate consignee and/or end-user(s) of the item. The DCS helps such parties understand that the items were exported under the U.S. export control system, so they will understand their responsibilities under the U.S. export control system. Ensuring that the DCS is placed on the document that has the greatest likelihood of reaching the parties that will ultimately receive and use the item is the best way to protect the interest of *all* parties that participate in exports that are subject to the EAR and ITAR. This includes exporters of non-600 series and non-9x515 items under the EAR. An effective DCS is important for protecting U.S. national security and foreign policy interests. Parties outside the United States that will receive and use an item that is "subject to the EAR" or "subject to the ITAR" must be aware that the item was exported to them under the U.S. export control system in order to be able to comply with the EAR or the ITAR.

Objectives Achieved

Comment 5: Several commenters indicated the objectives of the proposed rule were achieved because of the following reasons: (1) Will eliminate confusion regarding which statement to use for shipments that include both items subject to the ITAR and items subject to the EAR, (2) incorporating the DCS into the commercial invoice will be much more likely to achieve the intended purpose of the DCS; and (3) having common text for the DCS will significantly simplify the export process.

BIS response: BIS agrees.

Objectives Partially Achieved

Comment 6: Better to create a second DCS for use with ITAR and "600 series" and mixed shipments.

BIS response: BIS disagrees. This suggestion would create unneeded complexity. The concerns raised by exporters of non-600 series and non-9x515 items can be addressed without creating separate forms for different types of items.

Comment 7: Harmonized text right step. But DCS requirements need to be identical to achieve the intended objective.

BIS response: BIS agrees. The intent was to have the DCS text be identical, so any slight differences are being harmonized. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, introductory text of paragraph (a), this final rule makes a conforming edit for text used to ensure the text is the same under the EAR and ITAR DCS. In the first sentence of paragraph (a) introductory text, this final rule is removing the term "shall" and adding in its place the term "must." This change is being made to harmonize the EAR text with the text used in the ITAR DCS rule. Commerce and State intended for these words to be the same, but the Commerce and State proposed rules differed, so BIS is making this change in the Commerce final rule. This inconsistency was identified in one of the comments, including the suggestion of adopting State's text because it was clearer regarding it being a requirement. BIS agrees.

Objectives Not Achieved

Comment 8: There should be some way to ensure that this DCS information is communicated to all parties involved and not just to the first party the items will be exported to in the transaction. Often the export occurs to a sales agent/reseller in the foreign country who will first receive the shipment, but they may not be the actual end-user and may be in a country that is not the ultimate destination.

BIS response: BIS agrees. BIS has added text as described below to address such scenarios, along with also providing guidance on how the DCS provisions interact with other EAR provisions, which was noted by several other comments as a concern with potential overreach.

Comment 9: This appears to be a case of harmonization for the sake of harmonization, and would appear to have the potential to create substantial confusion among recipients, impose significant burdens without a correspondingly significant benefit to the government.

BIS response: BIS disagrees. Several other commenters noted the concern in particular over mixed shipments and that the objectives of the rule would be met. BIS disagrees that there would not be benefits to the United States Government. An effective U.S. export control system requires effective reexport controls, which at its most basic level means reexporters understand that an item is subject to U.S. reexport controls. Ensuring that the DCS actually goes out of the U.S. and reaches the parties that will receive the items is key to the United States Government's ability to achieve its objectives in this area with the DCS.

Comment 10: Statement that commercial invoice and contractual documentation would be most likely to travel with shipment not necessarily correct.

BIS response: BIS disagrees. For the commercial invoice, several other commenters disagreed with this commenter's assertion. Requiring the DCS on contractual documentation was not adopted in this final rule, so that part of the comment is no longer applicable.

Decreases Burden

Comment 11: Single DCS statement will make it easier to automate because the same DCS will be used for EAR and ITAR shipments.

BIS response: BIS agrees.

Increases Burden

Comment 12: Changes to the DCS can be costly because it requires recoding the logic for each enterprise resource planning (ERP) system printing the DCS in the export control documentation. Some companies may have several different ERPs, which further increases the burden.

BIS response: The delayed effective date is intended to ease this initial burden of transitioning to the new DCS, which BIS expects will subside quickly and that over the mid to long term the DCS text will ease the burden. BIS acknowledges that there will be a minimal one-time burden on exporters as they need to update the DCS text on an existing document that already requires the DCS, but BIS expects this to be a one-time cost, not a recurring one. The delayed effective date of 90 days will also ease the cost on exporters who have already pre-printed the DCS on their commercial invoice documents by allowing such exporters to use that remaining stock of commercial invoices during the transition period prior to the effective date. In addition, several commenters noted that their systems are set up to prepopulate the commercial invoice, so limiting the requirement to the commercial invoice should ease the burden significantly. Current EAR DCS requirements already extend to the invoice (which has the same meaning as commercial invoice), so exporters' ERP systems should already be set up for this requirement and the extent of the change is limited to updating the text of the statement. Not adopting the proposed requirement to include the DCS on the contractual documentation will significantly reduce the amount of changes needed to ERP systems. This commenter also wanted the ability to continue to include the DCS on the shipping documents. Nothing in the final rule would prohibit continuing that practice, which will also reduce the number of changes needed to ERP systems, except for updating the text used.

Comment 13: Extending to intangible exports would create a significant burden.

BIS Response: BIS agrees. BIS has added changes in this final rule to clarify the EAR DCS is only required on the items exported in tangible form. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, introductory text of paragraph (a), this final rule clarifies that paragraph (a) applies only to items shipped, *i.e.,* exported in tangible form. As discussed above in response to the public comments, several commenters were concerned that the use of the defined term "export" would be a significant expansion of the DCS requirement by requiring the DCS for tangible as well as intangible exports. BIS had intended this broader scope when using the term "export," instead of the undefined term shipment, in the proposed rule. However, in reviewing the public comments and in discussing the practice under the ITAR, BIS accepts the public comments on the Commerce rule to clarify that the scope of the DCS requirement only applies to items on the Commerce Control List that are shipped (exported in tangible form). Therefore, this final rule adopts in paragraph (a)(1) the term "shipped (*i.e.,* exported in tangible form)" rather than the term "export."

In § 758.6, paragraph (a)(2), this final rule removes the term "exported" and adds in its place the phrase "shipped (*i.e.,* exported in tangible form)." This clarification is made for the same reasons why, as described above, the similar changes were made to paragraph (a)(1) in response to public comments.

Concerns About Costs To Implement

Comment 14: Large and small exporters will incur costs that are dependent on size, but significant in any case. Large exporters will have to retool their ERP systems to collect information they are not presently collecting (*e.g.*, end-user) and insert it into documents they do not currently generate with a DCS.

BIS response: The commenter is concerned about having to account for changes in the ERP system, but this concern is not warranted because the proposed rule did not change any of the obligations of the parties to the transaction in these situations under the EAR. BIS is clarifying that these obligations of the parties to the transactions will not change, which also addresses the ERP changes concern. These concerns about the extent of changes required to the ERP systems were based on an incorrect understanding that the obligations of the parties to the transactions were also proposed to change in addition to the DCS proposed changes. As discussed elsewhere in this final rule, BIS is clarifying that this is not the case.

Concerns With Proposed DCS Text

Comment 15: There is no justification for requiring the inclusion of the new DCS on documentation associated with NLR exports, as such exports require no authorization from the U.S. Government. Such a requirement would be unnecessarily burdensome and should be eliminated.

BIS response: BIS disagrees. The requirement to include the DCS for most NLR shipments is an existing EAR DCS requirement. An item that can be exported NLR to one country or one end user or end use may require an EAR license for subsequent transfers (in-country) or reexports. For example, NS1, RS1, or MT1 controlled items could go NLR to Canada, but would be subject to a worldwide license requirement for any subsequent reexport. Further, there are certain persons in Canada on the Entity List who are subject to a license requirement for all items subject to the EAR, including a license requirement for transfers (in-country). Merely because the initial export can be made under the NLR designation does not preclude that subsequent reexporters or transfers (in-country) will require a license. Accordingly, no new burden is being imposed because the existing DCS requirements require it for NLR designated shipments and the policy rationale for why a DCS is needed for NLR shipments has not changed.

Comment 16: Proposed rulemaking requires a DCS to be included whenever any item on the CCL is exported. Because exports are defined to include both tangible and intangible transfers, this requirement can be construed to require the DCS to be included on both physical shipments as well as intangible transfers (*e.g.*, when software is downloaded). They propose that the requirements should be limited to physical (tangible) exports only.

BIS response: BIS agrees. BIS has made changes in this final rule to clarify the DCS only applies to shipments (exports in tangible form). This final rule makes the following regulatory changes to address this public comment:

In § 758.6, paragraph (a)(1), this final rule removes an unneeded phrase. Specifically, this final rule removes at the beginning of paragraph (a)(1) the phrase "For any item on the Commerce Control List being exported" because the text is not needed. The text is not needed because the same text is already stated in the introductory text of paragraph (a). This will shorten and simplify the text of paragraph (a)(1) without changing the requirements of this paragraph, or the requirements specified in paragraph (a)(2).

Comment 17: Clarifying that the DCS provisions are limited to shipments (tangible exports).

BIS response: After reviewing the public comments, this final rule limits the requirement to shipments, *i.e.*, tangible exports, but notes that when a commercial invoice does exist for intangible exports that BIS recommends as a good compliance practice to include a DCS or other export control related information that may be relevant.

Comment 18: Retain the phrase "excluding EAR99 items" in the text of § 758.6 for maximum clarity.

BIS response: BIS agrees. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, introductory text of paragraph (a), this final rule clarifies that items designated as EAR99 do not require a DCS. The proposed rule in the preamble explained that items designated as EAR99 did not require the DCS, and several of the public commenters agreed. However, some of the commenters suggested that this clarification also needed to be added to the regulatory text in paragraph (a)(1). BIS believes the reference in the text of paragraph (a) to "items on the Commerce Control List" already clarifies that the requirement would not extend to items designated as EAR99. However, BIS does agree with the commenters that for people not familiar with the EAR, such as certain foreign purchasers or consignees that would be receiving commercial invoices with this DCS, that this nuance of the Commerce Control List may not be well understood and could lead to misunderstanding. BIS agrees that although the text may be slightly redundant that it will be helpful in particular for those not as familiar to the EAR, so the final rule is adding the phrase "or the item is designated as EAR99" to the introductory text of paragraph (a) to clarify items designated as EAR99 do not require a DCS.

Comment 19: Clarify whether the use of the term "end-user" in the proposed language implies the creation of a new regulatory requirement to identify all potential end-users on all documents for which a DCS is required.

BIS response: The term "end user" does not create a new regulatory requirement. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, paragraph (a)(1), this final rule removes the term "specified" before the phrase "country of ultimate destination." The use of the term "specified," raised concerns for several of the commenters regarding whether the inclusion of this term would change other obligations of the parties to the transaction in these situations under the EAR for how exports are treated, in particular for subsequent reexports or transfers (in-country). BIS did not intend to change the obligations of the parties to the transaction in these situations under the EAR. In order to address these concerns, BIS has removed the term "specified." BIS, to address the public comments in this area, in particular misunderstandings for how the text of paragraph (a)(1) would be applied in the EAR context, is including Note 2 to paragraph (a)(1) to clarify the application of the phrase "country of ultimate destination," along with adding two other notes for paragraph (a)(1) to address misunderstandings for how paragraph (a)(1) would be applied in the EAR context.

In § 758.6, paragraph (a)(1), this final rule is also adding the term "ultimate consignee" before the term "end-user," along with making the term "end-user" plural by adding an "s" to clarify that the requirement applies to the "ultimate consignee" or "end-user(s)." This final rule did not adopt the term "or consignee" that followed the term "end-user" in the proposed rule. Certain commenters requested clarification regarding to which consignees the requirement specified in paragraph (a)(1) was intended to apply, which the more specific text of "ultimate consignee or end-user(s)" addresses. To achieve the objectives of the DCS, the commercial invoice must be provided to those two types of consignees: ultimate consignee and end-user(s), as applicable.

Comment 20: Commercial invoice and shipping documents currently in most cases do not include end users.

BIS response: BIS is aware of this, but the commercial invoice is still deemed to be the most appropriate document to achieve the objectives of the DCS. BIS will be adding FAQs to the BIS Web site to provide additional application guidance on applying the DCS in different scenarios.

Comment 21: Insert the phrase "ultimate consignee or" before the term end user.

BIS response: BIS accepts this suggestion which may mitigate the concerns people have with needing to include the end user on every document that requires the DCS.

Comment 22: Delete the term "ultimate" before the term "destination" and delete the term "ultimate end user."

BIS response: BIS will delete the term ultimate before those two terms.

DCS Text Is Too ITAR Specific and Will Be Difficult To Understand in EAR Context

Comment 23: Clarify the application of the DCS text in the EAR context as it relates to other EAR provisions, such as shipments to distributors and NLR and multi-step shipments.

BIS response: Many of the commenters that raised concerns regarding the burden or other major concerns were focused on how the DCS text seemed more appropriate for the ITAR regulatory construct than the EAR regulatory construct. These commenters thought that this rule proposed broader changes than intended, and therefore several of them raised significant concerns. For example, they raised concerns about how shipments to distributors would be handled in light of the proposed DCS text. In order to address these concerns, BIS is defining some of the key terms used in the DCS text as they are interpreted in the EAR context, including providing some specific application examples, along with adding notes to clarify the applicability of the DCS requirements in the context of the EAR. These changes will address the various concerns in this area that commenters raised related to NLR shipments or multi-step transactions that consist of discrete controlled events (*e.g.*, "exported" to a distributor as one discrete controlled event, and then a subsequent "reexport" as another discrete controlled event under the EAR). The proposed rule did not change any of these other provisions under the EAR, but the proposed text of the DCS made some people worry how the text would be applied in the EAR context.

Comment 24: The proposed inclusion of the phrase "or as otherwise authorized by U.S. law and regulations" is more likely to cause confusion than the current DCS with respect to items that can be reexported NLR or under a license exception, and lead recipients erroneously to believe that all U.S.-origin items require a specific reexport license. Some exporters have tried to use phrases in export control contractual clauses that limit reexports "unless otherwise approved in writing by the U.S. government or authorized by U.S. law or regulation." Such phrases are understood by sophisticated reexporters, but they inevitably lead to questions about why a reexport license is required, when no export license was required in the first place.

BIS Response: To address this commenter's concern, this final rule includes several clarifications to key terms used, including a new note to define what is meant by "or as otherwise authorized by U.S. law and regulations." This final rule makes the following regulatory changes to address this public comment:

In § 758.6, addition of Note 3 to paragraph (a). This final rule adds Note 3 to paragraph (a) to clarify what is meant in the EAR context by the phrase "or as otherwise authorized by U.S. law and regulations." The note as of the effective date of this final rule will now acknowledge that the phrase includes not just license exceptions, but also shipments made under 'no license required' as well as reexports of foreign made items containing less than *de minimis* U.S. origin controlled content. Some of the commenters acknowledged that the use of this phrase was also explained in the preamble of the proposed rule. However, other commenters did not understand this nuance of this proposed regulatory text. Most of those commenters also requested that BIS make this nuance of the EAR more explicit in regulatory text, in particular to avoid people outside the United States incorrectly believing that the new Commerce DCS provisions were intended to change or limit the applicability of the EAR *de minimis* provisions, or the EAR direct product rule provisions. The Commerce DCS proposed rule did not intend to change any EAR related provisions related to *de minimis* or the direct product rule, which is also the case with the Commerce final rule published today. BIS agrees with the commenters that making the intended meaning of the phrase "or as otherwise authorized by U.S. law and regulations" clearer will help understanding of the DCS provisions in the EAR. Therefore, this final rule is adding Note 3 to paragraph (a)(1) to address these comments.

Concern That State and Commerce Documents Are Not Harmonized for DCS

Comment 25: Commerce and State should require the DCS on the same document(s).

BIS response: Commerce and State agree that, in addition to harmonizing the text of the DCS, the requirements regarding the documents on which it needs to be placed should be harmonized as well. Commenters supported the Commerce proposal of including it on the commercial invoice. After reviewing the public comments, Commerce and State agree that using the same document for the requirement is the best approach.

Comment 26: Export clearance phase of corporate export controls compliance programs relies heavily on information technology (IT) as standardization conserves resources and improves compliance. By having different DCS implementation requirements for the ITAR and EAR, the proposed regulation will force companies to have two different IT systems—one for the ITAR and one for the EAR. Companies will have to re-train their compliance staff to be able to determine which commercial document to insert the required DCS statement. This proposal will increase compliance costs. Different documents for DCS will increase likelihood of violations.

BIS Response: BIS agrees. BIS will require the DCS on the same document, the commercial invoice, as required by State.

Supports Using Commercial Invoice

Comment 27: Supports this proposed requirement and recognizes this change as a key element to reinforcing the intent of the regulation which is to provide the foreign consignee with needed information to ensure compliance with the EAR. The foreign consignee is far more likely to receive the commercial invoice and contractual documents between the shipper/USPPI and consignee/buyer than any transportation documentation produced by the carrier/forwarder for any such contract of carriage.

BIS response: BIS agrees. However, as noted elsewhere in this final rule, BIS is limiting the documentation requirement to the commercial invoice.

Comment 28: Exporters generate commercial invoices, but freight forwarders and/or carriers generate bills of lading and air waybills. Imposing requirements on exporters that they must then flow to other parties to a shipping transaction adds complexity and compliance risk.

BIS response: BIS agrees. The Commerce proposed rule already took these factors into account in proposing that the DCS be placed on the commercial invoice and contractual documentation (documents created by exporter). As described elsewhere in this final rule, the requirement is limited to the commercial invoice (document created by exporter).

Comment 29: Supports the approach taken by BIS for using commercial invoice and contractual documentation, and in particular for recognizing that this lengthy statement does not offer value on the transport document (bill of lading, air waybill) and that the DCS should be required only on the commercial and contractual documents that relate to the transactions between the vendors, purchasers and other parties that may be involved in the commercial relationship for exports.

BIS response: BIS agrees, but as noted elsewhere in the final rule the requirement will be limited to the commercial invoice.

Concerns With Using Commercial Invoice

Comment 30: Invoices are usually filed by the finance function that is responsible for payment and they may not take any action on this information (*e.g.,* restriction on further re-sale/transfer to the end-user); explicitly stating export restriction on the contractual documents would be a more effective way to communicate the importance of compliance with the U.S. exports regulation and use of the items.

BIS response: Other commenters did not support using contractual documentation. BIS notes that although the personnel involved in financial management of a company (*e.g.,* those in accounts payable) may receive the commercial invoice either at the time the items shipped (exported in tangible form) are received or before, at some point in the process typically the commercial invoice is matched up with what was received. If the DCS reaches the ultimate consignee or end-user(s) before the item is subsequently reexported or transferred (in-country) to another party, it helps to achieve the objective of putting the reexporter or transferor on notice that the items are subject to U.S. export controls.

Comment 31: BIS uses the term "commercial invoice" but DDTC uses the term "invoice." For some exporters, the term "invoice" refers to the final billing document that moves electronically, whereas the commercial invoice moves with the freight.

BIS response: BIS agrees that the terms should be harmonized. Based on other comments received, the term commercial invoice is well understood by industry, as well as by BIS's Office of Export Enforcement, so this final rule adopts the term commercial invoice.

Comment 32: Commercial invoices do not accompany items during shipment. In today's business processes, invoices are sent either electronically (the preferred method) or in hard copy directly to the buyer's accounts payable department. The invoice is not sent to those who might divert the items. In compliance with the EAR, the DCS is currently printed on the invoice, but doing so arguably does not serve the purpose BIS intends.

BIS response: Several other commenters supported BIS's position that the commercial invoice is the document most likely to travel to the end of the export. However, BIS acknowledges and understands that in certain cases a commercial invoice may be sent prior to the items being shipped (exported in tangible form), so this final rule does not specify the timing of when the commercial invoice must be sent, but simply specifies the requirement that the commercial invoice must include the DCS. BIS intends to add FAQs to the BIS Web site once this final rule is published to provide additional application guidance to exporters.

Comment 33: Changing requirement from "accompanies the shipment" to when "such documentation exists" is a significant expansion of the DCS requirement for little benefit to U.S. national security.

BIS response: BIS disagrees. As was noted by several commenters the DCS requirements under the EAR and ITAR we need to take into account how business is conducted in order for exporters to effectively comply and to achieve the export control objectives of protecting U.S. national security and foreign policy interests. Because the phrase "accompanies the shipment" is limiting and does not take into full account how documents are transmitted related to exports in certain cases, BIS does not accept the suggestion, which conflicts with the larger objectives of what the DCS provisions are trying to achieve.

Supports Using Contractual Documentation

Comment 34: The contractual documents and commercial invoice are intended to detail the entirety of the transaction between the parties that are engaging in the transfer of the items. Incorporating the DCS into those documents is much more likely to achieve the intended purpose of the DCS than is including that information on the air waybill.

BIS response: BIS agrees. However, as noted elsewhere in this final rule, BIS is limiting the documentation requirement to the commercial invoice.

Concerns for Using Contractual Documentation

Comment 35: The proposed requirement to include the DCS on contractual documentation raised significant concerns among the majority of commenters, even those that strongly supported the proposed rule. These commenters included a number of well supported reasons for why the use of contractual documentation would be needlessly burdensome and not achieve the stated objectives in the proposed rule. These reasons included the following: (1) The term "contractual documentation" was not defined and could be overinclusive of documents, including contractual documentation that are not related directly to items that would be exported, but would still create a significant administrative burden in keeping track of certain contractual documentation that would require the DCS from those that would not; (2) grandfathering of existing contractual documentation, where some commenters noted that amending existing contracts to include the DCS would require amending thousands of contractual documents; (3) would require a U.S. company to have prior knowledge during negotiations for what the item that is subject to the contract that will actually be exported, which often is unknown at the time a contract is signed; (3) handling changes in classification that may impact previous contracts would require contractual documents to be revised; (4) including the DCS in contractual documentation may exacerbate foreign parties' concerns over acknowledging U.S. extraterritoriality; and (5) if the ultimate goal of the proposed rule is to avoid diversion, most commenters noted that requiring the DCS to be included on the commercial invoice will suffice—meaning the objectives of the DCS could be achieved more efficiently by only requiring it on the commercial invoice without creating the significant burdens that would be required to include it on contractual documentation.

BIS response: Commerce and State agree with the public commenters that removing the requirement to include the DCS on the contractual documentation is warranted. The public comments were persuasive that including a requirement to include the DCS on the contractual documentation would create a significant amount of unneeded complexity and in most cases would not achieve the stated objectives in the Commerce and State proposed rules. Based on the public comments received and additional review by Commerce and State, limiting the requirement to include the DCS on the commercial invoice is sufficient to meet the stated objectives in the Commerce and State proposed rules, and therefore this final rule does not adopt the proposed requirement to include the DCS on contractual documentation. This final rule makes the following regulatory changes to address this public comment:

In § 758.6, introductory text of paragraph (a), this final rule removes the undefined term "contractual documentation." As discussed above, there was considerable concern raised regarding the inclusion of the undefined term "contractual documentation." BIS is not including the undefined term "contractual documentation" and instead, as explained above, is limiting the requirement under the EAR to the commercial invoice. The Department of State will only require the DCS to be placed on the commercial invoice under the ITAR.

Create a New Document Specific To Export Controls for Use With DCS

Comment 36: Provide the DCS and other export control information (*e.g.,* as "600 series" or a 9x515 ECCN classification) on a completely separate document that can serve multiple purposes and can be sent with the items being shipped or separately in order to convey to the consignees that the items are U.S. export regulated and are intended only for the designated end user and the destination identified. This should be similar to a certificate of compliance or documents of similar nature (usually from a quality perspective) that are usually sent to customers.

BIS response: BIS appreciates the effort this commenter put into the idea, including the templates they created, but ultimately BIS believes that it would be unduly burdensome to create a requirement to generate a wholly new document. Therefore, although we acknowledge there would be some benefits to what the commenter had in mind, BIS believes that it is still preferable to require the DCS on an existing document (the commercial invoice) that is created in the normal course of business. Other public comments support this conclusion.

Allow Flexibility for Exporters To Decide Which Document To Include DCS on, but Require It on One Document That Accompanies Physical Shipment

Comment 37: The regulations should not prescribe the specific document that must include the DCS, but instead require that it appear on one document that accompanies the item to the ultimate destination. Which document will contain the DCS should be determined by the exporter in light of its shipping practices.

BIS response: BIS disagrees. This would create a burden on exporters and other parties to the transaction, as well as the United States Government in conducting checks to confirm that exporters are in compliance. Allowing for exporters to pick and choose the document would create more burden than benefits that would come from allowing that level of flexibility because exporters and other parties to the transaction would need to adopt processes to identify on a transaction by transaction basis, which document contained the required DCS. Variability would provide flexibility, but also impose implementation costs. Requiring and identifying a single document, the commercial invoice, creates predictability, will facilitate the adoption of standardized processes and will reduce implementation costs. In addition, exporters are free to place the DCS on additional documents, but at a minimum the final rules published today by Commerce and State require the DCS to be placed on the commercial invoice.

Suggested Notes To Add to DCS Section

Comment 38: In the Supplementary Information, BIS states that, ". . . in the context of this EAR paragraph "authorized" would also include exports that were designated under No License Required (NLR)." This would be useful information to include in § 758.6.

BIS response: BIS agrees. BIS has added a note to specify this concept as described earlier in the BIS response above to Comment 6.

Other Changes To Enhance Usefulness of DCS in Preventing Diversions

Comment 39: A requirement should be added that all the parties (consignees involved in the transaction between the U.S. exporter and the ultimate end user) should somehow be communicated to about the U.S. regulations restricting further export/transfer to anyone or to any country other than the end user and ultimate destination should be considered in the final export process.

BIS response: Based on other comments received there would likely be significant concern about the burden created and the complexity of compliance programs caused by implementing such a requirement. The parties helping to facilitate the movement of the item to the end of the export are simply moving the item to the ultimate consignee or end user(s). The focus of the DCS on the commercial invoice is to ensure that it reaches the ultimate consignee and/or end user(s) that will be in a position to make a subsequent reexport or transfer (in-country), so they are aware the item in question is subject to U.S. reexport controls. As discussed in other parts of this rule, BIS is defining some of the terms used in the DCS text and adding some clarifying notes to provide additional context for how the DCS is applied in the EAR context.

Request for Delayed Effective Date

Comment 40: Requests that BIS strongly consider setting the implementation date 180–240 days after publication of the final rule to allow sufficient time for all affected parties to make the required changes to system programming, document revision and related procedural tasks. Other commenters had requested a 180 day delayed effective date, along with a delayed compliance date.

BIS response: Commerce and State agree that a delayed effective date is warranted and will delay the effective date of this final rule for 90 days after publication. This delay of effective date will allow exporters, as well as other parties to which these revised DCS requirements will apply, to make any needed changes to their export compliance systems and business processes.

Request for Public Meetings or Additional Proposed Rules Prior to Final Rule Publication

Comment 41: Request for public meetings for public to comment and requests for Commerce and State outreach for the new changes to be implemented.

BIS response: BIS values public participation in the rulemaking process. Through the public comment process, BIS has provided adequate opportunity for comment and has addressed the concerns that were raised. Therefore, BIS does not accept the request to conduct public meetings prior to publishing a final rule. In regard to the request for conducting outreach, BIS agrees that this is a good idea and intends to add updated DCS information to our already robust ECR related outreach activities, including to instruction at seminars and to the Frequently Asked Questions on the BIS Web site.

Comment 42: A public comment period with relevant meetings will provide the necessary fora to engage with the government and discuss mutually-beneficial alternatives to accomplish the government's objectives without putting any sector of the trade at an inappropriate disadvantage.

BIS response: Commerce and State already provided an opportunity for public review and comment on the proposed rules. Commerce and State have considered those public comments, which were generally supportive of the rule, and for those commenters that raised concerns, Commerce and State were able to refine what was proposed to address those comments and better achieve the stated objectives. Therefore, there is no need for an additional proposed rule or engaging in public meetings before moving forward with final rules, which would delay the reductions in burdens included in the Commerce and State final rules, as well as delaying the benefits for better protecting U.S. national security and foreign policy interests by adopting these more effective DCS requirements under the EAR and the ITAR. No party will be placed at an inappropriate disadvantage as a result of this rule being published in final form because all interested parties had an opportunity to review the proposed rule and make comments for improving the proposed DCS requirements. BIS by addressing those comments in this final rule has led to an improved rule that better achieves the stated objectives. As noted above, Commerce and State have a robust outreach program for ECR related changes and intend to conduct robust outreach regarding the new DCS requirements included in the final rules published today, in particular during the 90 day transition period prior to the effective date.

Including "600 Series" and 9x515 ECCNs on Same Documents as DCS

Comment 43: Require the items level classification for 9x515 and "600 series" items. In consideration that sub-categories of a same ECCN may not be subject to the same controls (for instance 9A610.x and 9A610.y.1), we suggest that the text be amended to request not only the ECCN, but also the corresponding subcategory.

BIS response: This comment is outside the scope of the proposed DCS rule.

Comment 44: While the requirement to place the DCS found in § 758.6(a)(1) on the commercial invoice is reasonable, the requirement to place the DCS and the ECCN for "600 series" or 9x515 item, when required, on contractual documentation, when such contractual documentation exits, may require a level of specificity that is not available at the time of contracting. The suggested change would clarify that the contract itself need not contain each "600 series" or 9x515 ECCN if subsequent contract implementing documentation will be the vehicle by which actual commitments for shipment of such items are made.

BIS response: As noted elsewhere in this final rule (*see* BIS response above to Comment 35 under the heading Concerns for using contractual documentation), BIS is not including contractual documents in the final rule, so this comment is no longer applicable.

Broadening Scope of DCS To Also Alert People Receiving Incorporated 9x515 and "600 Series" of Such Content

Comment 45: There is no requirement to include a DCS for end items that include ECCN 9x515/600 series de minimis content. This creates a risk related to restrictions on the use of de minimis for Country Group D:5 countries. For example, a non-U.S. prime may receive a system or sub-assembly from an Asian or European supplier for integration into an end-item. That system or sub-assembly may contain ECCN 9x515/600 series de minimis content from another supplier. The non-U.S. prime may never know about the ECCN 9x515/600 series content since there is no requirement for the re-exporter to disclose this information, which may raise a compliance issue when considering further retransfer to Country Group D:5 countries.

BIS response: This comment is outside the scope of the DCS proposed rule, but it is something that BIS will evaluate further. However, as a best practice, BIS does encourage companies to work together to assist each other in complying with the EAR requirements, whether that is in the United States or outside the United States when items that may be subject to the EAR are involved.

Add Provisions To Rescind Previous License Conditions for Currently Valid Licenses That Include a Condition That Current DCS Needed To Be Included on Current DCS Required Documents

Comment 46: Recommend a statement in a final rule to clarify that for existing, valid licenses previously issued by BIS, any license condition to place a DCS on any shipping documentation (*e.g.*, on all bills of lading or air waybills) not specifically required in the revised EAR is rescinded. A common current license condition is as follows: "Place a Destination Control Statement on all bills of lading, air waybills, and commercial invoices." This clarification will relieve exporters with numerous licenses, wherein the license condition to apply DCS to shipping documentation appears, from the need to petition the Commerce Department for relief from the condition.

BIS response: BIS confirms that a condition on a license issued prior to August 17, 2016 to place a destination control statement on documents other than the commercial invoice would no longer be applicable as of November 15, 2016.

Summary of the Regulatory Changes Being Made in This Final Rule to § 758.6

The heading of § 758.6 of the EAR remains the same. However, the provisions that were under paragraph (b) prior to the effective date of this final rule are being moved to a new paragraph (a)(2). Further, new paragraph (a)(2) specifies that the ECCN for each 9x515 or "600 series" item being shipped (exported in tangible form) must be included. This is the same requirement that was in paragraph (b) prior to the effective date of this final rule, although it is slightly shortened because the introductory text of paragraph (a) is specifying some of the requirements that previously were included in paragraph (b), specifically the documents for which the 9x515 and "600 series" classification must be included under this section. The commercial invoice is the same document that the DCS is included on, so this change is shortening and simplifying this section by moving the text of paragraph (b) to paragraph (a)(2). This change will reduce the number of documents upon which this classification needs to be included on to conform with the DCS changes described below.

The introductory text paragraph (a) in this final rule specifies that the exporter shall incorporate the information specified under paragraphs (a)(1) (destination control statement) and (a)(2) (ECCN for 9x515 or "600 series" item being shipped (exported in tangible form)) as an integral part of the commercial invoice. The changes in this final rule mean this section of the EAR no longer includes, as of the effective date of this final rule, a requirement to include the DCS on the air waybill, bill of lading or other export control documents, and instead is limiting the requirement to the commercial invoice.

Consistent with the DCS provisions prior to the effective date of this final rule, this final rule is not requiring an EAR DCS for exports of EAR99 items or items exported under License Exception BAG or GFT. Any other shipment (tangible export) from the United States of any item on the CCL would require the DCS as specified in paragraph (a)(1) and any shipment (tangible export) of a 9x515 or "600 series" ECCN would also need to be specified on the commercial invoice as specified in paragraph (a)(2).

The text of the harmonized DCS in this final rule is being specified under revised paragraph (a)(1) of § 758.6 of the EAR. The new DCS this final rule adds does not include EAR-specific language, but rather adopts text that is equally applicable under the ITAR as well as the EAR. However, this final rule adds several clarifying notes to clarify how the DCS provisions are applied in the EAR context. The first sentence of the statement added by this final rule specifies that "these items are controlled by the U.S. Government and authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified." For clarification this final rule moved the position of the phrase "by the United States Government" to the first sentence. This is a clarification to ensure that exporters understand that "only" modifies "authorized" and not "controlled." This first sentence is intended to alert the person outside the United States receiving the item that the item is subject to U.S. export laws and regulations and was authorized by the U.S. Government for export. In addition, the first sentence in this final rule specifies that the items are authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s). The new DCS included in this final rule uses the term authorized, but in the context of this EAR paragraph "authorized" would also include exports that were designated under No License Required (NLR). This final rule adds a new Note 1 to paragraph (a) to specify this in the regulatory text in regards to the applicability of NLR. This final rule adds Note 2 to paragraph (a) to specify the phrase "country of ultimate destination" means the country specified on the commercial invoice where the ultimate consignee or end user will receive the items as an "export." This note will assist the exporter's understanding of the use of this phrase in the context of the EAR.

The second sentence of the new harmonized DCS being added in this final rule focuses on alerting the persons receiving the items that they may not be resold, transferred, or otherwise be disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations. Similar to the first sentence, this second sentence is adopting common text that can be used under the ITAR and the EAR. The application of this second sentence is different under the ITAR and the EAR due to the different types of authorizations and other approvals in the respective regulations, as well as other differences, such as the *de minimis* requirements in the EAR, which is not provided for in the ITAR. The final rule adds a new Note 3 to paragraph (a) to make this clearer in regards to how this is applied in the EAR context.

The advantage of the text included in this final rule is that it adopts a new harmonized DCS, while at the same time is still flexible enough to not impact other ITAR or EAR provisions that do warrant differentiation, such as the availability of *de minimis* provisions, which are available under the EAR.

Adopting a new harmonized DCS in the final rule will simplify export clearance requirements for exporters because they will not have to decide which DCS to include, especially for mixed shipments containing both ITAR and EAR items.

As of the effective date of the Commerce and State final rules, an exporter will still need to go through all of the steps to determine jurisdiction, classification, and license requirements, and to obtain and use the proper authorization under the respective regulations, prior to moving on to the respective export clearance requirements under the ITAR or EAR. It is important to remember when reviewing the changes included in the Commerce and State final rules that the regulations still need to be reviewed and evaluated in the context in which they are intended to be applied, including the steps for determining the applicable export control requirements under the ITAR and the EAR. For those parties outside the United States that will be receiving items under this new DCS once this final rule becomes effective on November 15, 2016, although the new DCS is not ITAR or EAR specific, in the case of the ITAR the classification of USML items will be required on the commercial invoice. This classification will alert the parties that the items are subject to the ITAR. For military items under the EAR, because of the requirement this final rule is including in paragraph (a)(2) (which was required under paragraph (b) prior to the effective date of this final rule) of § 758.6 of the EAR, anyone receiving a "600 series" military item or an ECCN 9x515 item will know that item is subject to the EAR because the classification information will also need to be included on the commercial invoice. For other EAR items, there is not a requirement to include the classification information, although BIS does encourage the inclusion of that information as an export compliance best practice.

Removal of Paragraph (c)

BIS in this final rule removes the text that was in paragraph (c) of § 758.6 prior to the effective date of this final rule. BIS did not receive any comments on this proposed change and therefore is implementing this change in this final rule. Paragraph (c) was added recently (January 23, 2015, 80 FR 3463) and required prior to the effective date of this final rule a special DCS for items controlled under ECCNs for crime control columns 1 and 3 reasons or regional stability column 2 reasons when those items are destined to India. BIS proposed removing this requirement because the benefit of this requirement in paragraph (c) is outweighed by the added complexity to the EAR of including this country specific requirement. Therefore, consistent with the purpose of the retrospective regulatory review, BIS removes paragraph (c).

This final rule is the same as the May 22, 2015 proposed rule except for the refinements explained above. These changes address the public comments and will achieve the objectives of adopting a harmonized DCS requirement under the EAR and ITAR. These changes will help to further achieve the objectives of ECR to harmonize provisions between the EAR and the ITAR where warranted.

The changes in this final rule will ease the regulatory burden and complexity for exporters, in particular those with mixed shipments, which as noted above is now a much more common occurrence because of ECR. These changes and the corresponding reduction of documents that will require the DCS (now limited to the commercial invoices) will benefit all exporters under the EAR, not just exporters of "600 series" and 9x515 items. The DCS provisions in this final rule will better achieve their stated objectives—meaning all exporters will benefit because the appropriate parties (consignees in a position to make a subsequent reexport or transfer (in-country)) further down the line in export transactions will be receiving the DCS and other export control information required under this section as applicable.

These changes to the DCS provisions under the EAR and the ITAR move beyond harmonization for the sake of harmonization, which as discussed above was a concern of several of the commenters in response to the proposed rule. The changes in this final rule achieve true harmonization in this area of the U.S. export control system under the EAR and the ITAR, while at the same time improving the effectiveness of these provisions under the EAR and the ITAR, which ultimately will lead to better informed parties to transactions that are subject to U.S. export controls and better protecting U.S. national security and foreign policy interests. For the reasons described above, Commerce and State are publishing these final rules today.

As required by Executive Order (E.O.) 13563, BIS intends to review this rule's impact on the licensing burden on exporters. Commerce's full retrospective regulatory review plan is available at: *http://open.commerce.gov/news/2011/08/23/plan-analysis-existing-rules.* Data are routinely collected on an ongoing basis, including through the comments to be submitted and through new information and results from Automated Export System data. These results and data have formed, and will continue to form, the basis for ongoing reviews of the rule and assessments of various aspects of the rule. As part of its plan for retrospective analysis under E.O. 13563, BIS intends to conduct periodic reviews of this rule and to modify, or repeal, aspects of this rule, as appropriate, and after public notice and comment. With regard to a number of aspects of this rule, assessments and refinements may be made on an ongoing basis. This is particularly the case with regard to possible modifications that will be considered based on public comments described above.

Export Administration Act

Although the Export Administration Act expired on August 20, 2001, the President, through Executive Order 13222 of August 17, 2001, 3 CFR, 2001 Comp., p. 783 (2002), as amended by Executive Order 13637 of March 8, 2013, 78 FR 16129 (March 13, 2013) and as extended by the Notice of August 4, 2016, 81 FR 52587 (August 8, 2016), has continued the Export Administration Regulations in effect under the International Emergency Economic Powers Act. BIS continues to carry out the provisions of the Export Administration Act, as appropriate and to the extent permitted by law, pursuant to Executive Order 13222, as amended by Executive Order 13637.

Rulemaking Requirements

1. Executive Orders 13563 and 12866 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distribute impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been determined to be significant for purposes of Executive Order 12866.

2. Notwithstanding any other provision of law, no person is required to respond to, nor is subject to a penalty for failure to comply with, a collection of information, subject to the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*) (PRA), unless that collection of information displays a currently valid OMB control number. This regulation involves collections previously approved by the OMB under control number 0694–0122, "Licensing Responsibilities and Enforcement." This rule does not alter any information collection requirements; therefore, total burden hours associated with the PRA and OMB control number 0694–0122 are not expected to increase as a result of this rule. BIS acknowledges that there will be a minimal one-time burden on exporters as they need to update the DCS text on an existing document that already requires the DCS, but BIS expects this to be a one-time cost, not a recurring one. The scope of the text change, which is very similar in length to the current DCS, should be easy to implement based on the public comments received that strongly favored using the commercial invoice for the DCS requirement. You may send comments regarding the collection of information associated with this rule, including suggestions for reducing the burden, to Jasmeet K. Seehra, Office of Management and Budget (OMB), by email to *Jasmeet_K._Seehra@omb.eop.gov,* or by fax to (202) 395–7285.

3. This rule does not contain policies with Federalism implications as that term is defined under E.O. 13132.

4. The Regulatory Flexibility Act (RFA), as amended by the Small Business Regulatory Enforcement Fairness Act of 1996 (SBREFA), 5 U.S.C. 601 *et seq.,* generally requires an agency to prepare a regulatory flexibility analysis of any rule subject to the notice and comment rulemaking requirements under the Administrative Procedure Act (5 U.S.C. 553) or any other statute, unless the agency certifies that the rule will not have a significant economic impact on a substantial number of small entities. Under section 605(b) of the RFA, however, if the head of an agency certifies that a rule will not have a significant impact on a substantial number of small entities, the statute does not require the agency to prepare a regulatory flexibility analysis. Pursuant to section 605(b), the Chief Counsel for Regulation, Department of Commerce, certified to the Chief Counsel for Advocacy, Small Business Administration that the May 22 proposed rule, if promulgated, will not have a significant impact on a substantial number of small entities. A summary of the factual basis for the certification was provided in the May 22 proposed rule that is being finalized in this rule and is not repeated here. No comments were received regarding the economic impact of this final rule. Consequently, BIS has not prepared a regulatory flexibility analysis for this final rule.

List of Subjects in 15 CFR Part 758

Administrative practice and procedure, Exports, Reporting and recordkeeping requirements.

Accordingly, part 758 of the Export Administration Regulations (15 CFR parts 730–774) is amended as follows:

PART 758—[AMENDED]

■ 1. The authority citation for part 758 is revised to read as follows:

Authority: 50 U.S.C. 4601 *et seq.;* 50 U.S.C. 1701 *et seq.;* E.O. 13222, 66 FR 44025, 3 CFR, 2001 Comp., p. 783; Notice of August 4, 2016, 81 FR 52587 (August 8, 2016).

■ 2. Section 758.6 is revised to read as follows:

§ 758.6 Destination control statement and other information furnished to consignees.

(a) The exporter must incorporate the following information as an integral part of the commercial invoice whenever items on the Commerce Control List are shipped (*i.e.,* exported in tangible form), unless the shipment (*i.e.,* the tangible export) may be made under License

Exception BAG or GFT (see part 740 of the EAR) or the item is designated as EAR99:

(1) The following statement: "These items are controlled by the U.S. Government and authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations" and

(2) The ECCN(s) for any 9x515 or "600 series" "items" being shipped (*i.e.*, exported in tangible form).

Note 1 to paragraph (a). In paragraph (a)(1), the term 'authorized' includes exports, reexports and transfers (in-country) designated under No License Required (NLR).

Note 2 to paragraph (a). The phrase 'country of ultimate destination' means the country specified on the commercial invoice where the ultimate consignee or end user will receive the items as an "export."

Note 3 to paragraph (a). The phrase 'or as otherwise authorized by U.S. law and regulations' is included because the EAR contain specific exemptions from licensing (*e.g.*, EAR license exceptions and NLR designations) and do not control the reexport of foreign-made items containing less than a de minimis amount of controlled content. See § 734.4 and Supplement No. 2 to part 748.

(b) [Reserved]

Dated: August 8, 2016.

Kevin J. Wolf,

Assistant Secretary of Commerce for Export Administration.

[FR Doc. 2016–19551 Filed 8–16–16; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 120, 123, 124, 125, and 126

[Public Notice: 9606]

RIN 1400–AC88

Amendment to the International Traffic in Arms Regulations: Procedures for Obtaining State Department Authorization To Export Items Subject to the Export Administration Regulations; Revision to the Destination Control Statement; and Other Changes

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: As part of the President's Export Control Reform (ECR) initiative, the Department of State is amending the International Traffic in Arms Regulations (ITAR) to clarify rules pertaining to the export of items subject to the Export Administration Regulations (EAR), revise the destination control statement in ITAR § 123.9 to harmonize the language with the EAR, make conforming changes to ITAR §§ 124.9 and 124.14, and make several minor edits for clarity.

DATES: This rule is effective November 15, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. C. Edward Peartree, Director, Office of Defense Trade Controls Policy, Department of State, telephone (202) 663–2792; email *DDTCResponseTeam@state.gov.* ATTN: Regulatory Change, Destination Control Statement.

SUPPLEMENTARY INFORMATION: The Department published a proposed rule on May 22, 2015 (80 FR 29565) and received 17 public comments on the proposed changes to the ITAR. The Department makes the following revisions in this final rule:

Items Subject to the EAR

This final rule adds clarifying language to various provisions of the ITAR pertaining to the use of exemptions to the license requirements and the export of items subject to the EAR, when the EAR items are shipped with items subject to the ITAR. These revisions include guidance on the use of license exemptions for the export of such items, as well as clarification that items subject to the EAR are not defense articles, even when exported under a license or other approval, such as an exemption, issued by the Department of State. The Department received the following comments on the proposed changes, which are summarized here, along with the Department's responses:

One commenter raised a concern that the proposed revised language restricts industry's exemption options for items subject to the EAR to situations only when related USG authorization exists for the end item. The Department accepts the comment and has revised § 120.5(b) to state that items subject to the EAR may be exported pursuant to an ITAR exemption if exported with defense articles. ITAR exemptions may not be used for the independent export of items subject to the EAR, *i.e.*, a single physical shipment of EAR item(s) that does not include any USML item with which the EAR item may be used. If the items subject to the EAR will be transferred separately from a defense article, license exceptions available under the EAR may be used to authorize the transfer.

One commenter noted that, the proposed § 120.5(b) inadvertently excluded the exemptions at Part 123 of the ITAR from the parenthetical list of applicable ITAR parts. The Department concurs with this comment and adds a reference to part 123 into the parenthetical phrase.

One commenter noted that the Department should provide clarification and guidance on the proper classification to be entered into the Automated Export System (AES) for items subject to the EAR shipped under an ITAR exemption. The commenter noted that proposed edits to § 123.9(b)(2) did not address AES filings. The Department notes that the Department of Commerce (U.S. Census Bureau and Bureau of Industry and Security) has already clarified this. The EAR classification needs to be provided in the export control information on the Electronic Export Information (EEI) filing in AES for all items subject to the EAR, including EAR99 designated items that are authorized for export under a State Department authorization.

One commenter noted that the changes in this rule require that if a shipment includes both ITAR and EAR controlled items then the Export Control Classification Number (ECCN) of items in the shipments must be listed, including any EAR99 designation (if the authorization for the export was through an approved State Department license), and requires the country of ultimate destination, end-user, licensee information to be provided on the export documents. The flexibility of exporting items subject to the EAR under a State Department authorization does warrant this additional level of identification for all of the items subject to the EAR that the Department authorizes for export. Therefore, although the Department understands the comment, given the hybrid nature of the ITAR authorization under the § 120.5(b) process, the Department has determined the requirements are warranted.

One commenter noted that the text under § 120.5(b) does not specify that "items subject to the EAR" exported under an exemption must be exported with the specific defense article. They recommend clarifying that this is the intent of the modification or if not, to change the text, so it comports with the requirements for "items subject to the EAR" exported under a license or other approval. The Department concurs with this comment. This final rule adds clarifying text to § 120.5(b) to specify that in order to use a Department of State license exemption the item subject to the EAR must be exported with a defense article.

Items Exported To or On Behalf of an Agency of the U.S. Government

This final rule does not revise the licensing exemption language in § 126.4. This section will be addressed in a separate rulemaking and comments submitted in response to the proposed rule on that topic will be addressed in that rulemaking.

Revision to the Destination Control Statement

This final rule revises the Destination Control Statement (DCS) in ITAR § 123.9 to harmonize the text with the text of the DCS in EAR § 758.6, which is the subject of a companion rule to be published by the Department of Commerce. The DCS revision is also reflected in § 124.9 and 124.14. This change is being made to facilitate the President's Export Control Reform initiative, which has transferred thousands of formerly ITAR-controlled defense article parts and components, along with other items, to the Commerce Control List in the EAR, which is under the jurisdiction of the Department of Commerce. This change in jurisdiction for many parts and components of military systems has increased the incidence of exporters shipping articles subject to both the ITAR and the EAR in the same shipment. Both regulations have a mandatory Destination Control Statement that must be on the export control documents for shipments that include items subject to both sets of regulations. This had previously caused confusion to exporters as to which statement to include on mixed shipments, or whether to include both. Harmonizing these statements will ease the regulatory burden on exporters.

Summary of Public Comments on the Destination Control Statement

Most of the public comments fell into one of four areas: (1) Harmonization of DCS language between the ITAR and the EAR; (2) harmonization of documentation between the ITAR and EAR; (3) providing exporters a sufficient implementation period to adjust to the new DCS requirements; and (4) consideration of the different documents required for shipping, with the commercial invoice being the clear favorite and most appropriate for the DCS to be included on.

This final rule includes an effective date 90 days after publication in the **Federal Register** for the DCS provisions. It also specifies that the exporter is responsible for including the DCS on the commercial invoice. Additionally, the DCS text adopted in this final rule is identical to the DCS text adopted in a companion rule by Commerce.

The Department received a small number of comments on the proposed rule which were specific to the Commerce proposed rule, and Commerce is addressing these comments in its final rule.

Public Comments and the Department's Responses

Several commenters noted that harmonization represents a step in the right direction and will minimize confusion as to which DCS must be used depending on the jurisdiction of the item. The Department concurs with this comment.

Several commenters objected that the Department's requirements for placement of the DCS were out of step with Commerce and not harmonized in the proposed rule. The Department agrees, and the requirement for placement of the DCS is being harmonized by the Departments of State and Commerce.

Several commenters stated that the government should not specify the documents that require the DCS, but rather should impose a high level requirement and leave it to parties to choose which document(s) to include. The Department disagrees. Specifying which documents the DCS will be placed on will create greater transparency, as well as make it easier for various United States government agencies, as well as exporters and other consignees, to identify whether the DCS has been properly included.

One commenter noted that this appears to be a case of harmonization for the sake of harmonization, and would appear to have the potential to create substantial confusion among recipients, and impose significant burdens without a correspondingly significant benefit to the government. The Department disagrees. Ensuring the DCS reaches the parties that will receive items exported and/or reexported is key to the United States achieving its policy objectives.

One commenter stated that it was confusing that Commerce uses the term "commercial invoice" whereas the Department uses "invoice." For some exporters, the term "invoice" refers to the final billing document that moves electronically, whereas the commercial invoice moves with the freight. The Department agrees that the terms should be harmonized. Based on other comments received, the term "commercial invoice" is well understood by industry, so this final rule adopts the term "commercial invoice" to reference the document that moves with the freight.

One commenter objected to the DCS, as it imposed additional burdens and costs on the public and trade. Further, the commenter noted that to add this information separately to the bill of lading, air waybill and other transportation documentation could have the unintended effect of signaling the package contents to third parties. The Department disagrees with the commenter's characterization as these statements are already required and the harmonization of the DCS will lower the administrative burden on exporters and re-exporters. In addition, and as noted elsewhere in this final rule, the Department is removing the requirement to include the DCS on transportation documents.

One commenter stated that the air waybill imposed a severe space limitation with regard to including the DCS. According to the commenter, including information regarding a country of ultimate destination, end-user, and license or other approval number or exemption citation information could be unduly burdensome. The Department concurs, as noted elsewhere in this final rule, and the requirement to include the DCS on transportation documents has been removed.

One commenter noted that the State Department should consider a shorter DCS, such as: "This shipment contains goods under the jurisdiction of the ITAR." This statement could more easily be converted to an electronic format than the complete DCS. The Department disagrees, as an ITAR specific DCS would defeat the purpose of harmonization between the Departments of State and Commerce and would not address mixed shipments.

One commenter suggested that the DCS and other export control related information (*e.g.,* USML category) be placed on a separate document that serves multiple purposes, and can be sent with the items being shipped or separately in order to convey to the consignees that the items are U.S. export regulated and are intended only for the designated end user and the destination identified. The Department acknowledges there would be some benefits to such an approach, but it is preferable to require the DCS on an existing document (the commercial invoice) that is created in the normal course of business. Other public comments support this conclusion.

Numerous commenters requested a delay in the implementation date of between 180–240 days after publication of the final rule to allow sufficient time for affected parties to make the required changes to system programming, document revision and related procedural tasks. Other commenters requested a 180 day delayed effective date, along with a delayed compliance date. The Department agrees that industry will need time to update their systems and has included a delayed effective date of 90 days after publication of this final rule.

One commenter requested public meetings in order to comment on the proposed changes, and that State and Commerce also conduct outreach prior to new changes being implemented. The Department values public participation in the rulemaking process and has provided an opportunity for public review and comment on the proposed rules. For those commenters that raised concerns, the Department was generally able to refine what was proposed to address those comments and better achieve the stated objectives. Therefore, the Department does not see a need to conduct public meetings prior to publishing this final rule. In regards to outreach, the Department agrees that this is a good idea and intends to add updated DCS information to our already robust ECR related outreach activities.

Overview of Regulatory Changes To Address Public Comments

The Department of State has revised the proposed changes to § 123.9 to address the public comments and to better achieve its stated objectives in this final rule. The public comment process was helpful in identifying areas where changes needed to be made to fully achieve the intended objectives for the DCS for use under the ITAR and the EAR.

Placement of Destination Control Statement. This final rule removes the requirement to place the Destination Control State on the bill of lading, air waybill, or other shipping documents and retains the requirement for the invoice, which will now be more clearly described as the commercial invoice. As stated elsewhere in this final rule, the commercial invoice is the document that is most likely to achieve the purpose of this section and therefore the Department is limiting the requirement to this one document, which also will reduce the burden on exporters.

Clarifying the scope of paragraph 123.9(a) applies to items shipped (exported in tangible form), retransferred (in tangible form), or reexported (in tangible form). This final rule clarifies that the requirement applies to tangible defense articles when exported, reexported, or retransferred.

Addition of Note to paragraph 123.9(b)(1)(iv). This final rule also adds a Note to proposed paragraph (b)(1)(iv) to clarify what is meant in the DCS by the phrase "or as otherwise authorized by U.S. law and regulations." The note clarifies that the phrase "or as otherwise authorized by U.S. law and regulations" is included to advise that U.S. regulations contain specific license exemptions, provisions that allow shipments to be made "no license required," as well as reexports of foreign made items containing less than de minimis U.S. origin controlled content (see 15 CFR 734). This note reflects that an individual license is not required in all cases.

Procedures for Obtaining State Department Authorization To Export Items Subject to the EAR

This final rule adds a new paragraph (d) to § 123.9 to clarify the requirements for retransferring items subject to the EAR pursuant to a request for written approval from DDTC.

Other changes in this rule. The Department makes a number of minor edits to the ITAR that address reporting requirements. This final rule removes the requirement to provide seven paper copies for various requests in §§ 124.7, 124.12, 124.14, 125.2, 125.7 and 126.9. The Department did not receive any comments on the proposed changes, except for one commenter that expressed support for the removal of unnecessary submission requirements (*e.g.,* seven paper copies). Therefore, this final rule revises §§ 124.7, 124.12, 124.14, 125.2, 125.7 and 126.9 as proposed.

This final rule imposes the Code of Federal Regulations paragraph structure on § 124.8. The Department received no comments on § 124.8, and the provision is adopted as proposed.

This final rule replaces the previous Destination Control Statement in § 124.9(a)(6) with the new language found at § 123.9(b)(1)(iv). The Department received only one comment on this issue, which did not propose substantive changes, but advised that § 124.9(a)(6) needed to reflect the new Destination Control Statement language. The Department notes that the proposed rule did not revise the Destination Control Statement language of § 124.14(c)(7). Therefore, this final rule revises §§ 124.9 and 124.14 accordingly.

This final rule also changes the identification of the agency responsible for permanent import authorizations in § 123.4 from the Department of the Treasury to Department of Justice. The Department did not receive any comments on the proposed changes. Therefore, this final rule revises § 123.4 as proposed.

This final rule removes the pilot filing requirement found in § 123.13, given that, as noted in the proposed rule, it did not take into account the practices of modern airport operations and is no longer necessary. The Department did not receive any comments on the proposed change. Therefore, this final rule revises § 123.13 as proposed.

This final rule revises § 124.12(b) to correct the citations contained in the parenthetical from §§ 124.9 and 124.10 to §§ 124.8 and 124.9. This revision was not included in the proposed rule.

Additionally, the Department amends § 126.9, Advisory Opinions and Related Authorizations, to add a new paragraph (c) for requests to interpret ITAR requirements. This revision was not included in the proposed rule but is added to clarify the Department's practice. The Department is undertaking a review of the advisory opinion process which will be addressed in a future rule.

Finally, the Department notes that this final rule does not revise the NATO special retransfer authorizations language in § 124.16, which was contained in the proposed rule. By separate **Federal Register** notice (81 FR 35611, June 3, 2016) effective September 1, 2016, the provisions of § 124.16 will be incorporated into § 126.18 and the section will be removed and reserved.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department of State is of the opinion that controlling the import and export of defense articles and services is a foreign affairs function of the United States government and that rules implementing this function are exempt from §§ 553 (rulemaking) and 554 (adjudications) of the Administrative Procedure Act (APA). Although the Department is of the opinion that this rule is exempt from the rulemaking provisions of the APA, the Department published this rule with a 45-day provision for public comment and without prejudice to its determination that controlling the import and export of defense services is a foreign affairs function. The Department has made additional refinements to what was proposed based on the public comments received, which helps to further the objectives described in the proposed rule that is published as a final rule today. The Department is also adopting a delayed effective date of 90 days.

Regulatory Flexibility Act

Since this final rule is exempt from the provisions of 5 U.S.C. 553, there is no requirement for an analysis under the Regulatory Flexibility Act.

Unfunded Mandates Reform Act of 1995

This rulemaking does not involve a mandate that will result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million or more in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

The Department does not believe this rulemaking is a major rule as defined in 5 U.S.C. 804.

Executive Orders 12372 and 13132

This rulemaking will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132, it is determined that this rulemaking does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement. The regulations implementing Executive Order 12372 regarding intergovernmental consultation on Federal programs and activities do not apply to this proposed rulemaking.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributed impacts, and equity). These executive orders stress the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has been designated a "significant regulatory action" under Executive Order 12866. Accordingly, this final rule has been reviewed by the Office of Management and Budget (OMB).

Executive Order 12988

The Department of State has reviewed this rulemaking in light of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Executive Order 13175

The Department of State has determined that this rulemaking will not have tribal implications, will not impose substantial direct compliance costs on Indian tribal governments, and will not preempt tribal law. Accordingly, the provisions of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose any new reporting or recordkeeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35. This rule removes provisions that previously required the applicant to provide seven additional copies for various export license requests. As noted in the proposed rule, the Department believes that there would be little or no practical burden reduction since the use of electronic methods of filing has made the requirement for "seven copies" obsolete. The Department requested public comment on its estimate that there will be little or no change in the burdens associated with effected information collections as a result of this rulemaking. The Department received no public comments with respect to the information collections.

List of Subjects

22 CFR Parts 120 and 125

Arms and munitions, Classified information, Exports.

22 CFR Part 123

Arms and munitions, Exports, Reporting and recordkeeping requirements.

22 CFR Part 124

Arms and munitions, Exports, Technical assistance.

22 CFR Part 126

Arms and munitions, Exports.

Accordingly, for the reasons set forth above, title 22, chapter I, subchapter M, is amended as follows:

PART 120—PURPOSE AND DEFINITIONS

■ 1. The authority citation for part 120 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2794; 22 U.S.C. 2651a; Pub. L. 105–261, 112 Stat. 1920; Pub. L. 111–266; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 2. Section 120.5 is amended by revising the section heading and paragraph (b) to read as follows:

120.5 Relation to regulations of other agencies; export of items subject to the EAR.

* * * * *

(b) A license or other approval (see § 120.20) from the Department of State granted in accordance with this subchapter may also authorize the export of items subject to the EAR (see § 120.42). An exemption (see parts 123, 124, 125, and 126 of this subchapter) may only be used to export an item subject to the EAR that is for use in or with a defense article and is included in the same shipment as any defense article. No exemption under this subchapter may be utilized to export an item subject to the EAR if not accompanied by a defense article. Separate approval from the Department of Commerce is not required for these items. Those items subject to the EAR exported pursuant to a Department of State license or other approval would remain under the jurisdiction of the Department of Commerce for any subsequent transactions. The inclusion of items subject to the EAR on a Department of State license or other approval does not change the licensing jurisdiction of the items. (See § 123.1(b) of this subchapter for guidance on identifying items subject to the EAR in a license application to the Department of State.)

PART 123—LICENSES FOR THE EXPORT AND TEMPORARY IMPORT OF DEFENSE ARTICLES

■ 3. The authority citation for part 123 continues to read as follows:

Authority: Secs. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2753; 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261, 112 Stat. 1920; Sec. 1205(a), Pub. L. 107–228; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 4. Section 123.4 is amended by revising paragraph (a)(4) to read as follows:

§ 123.4 Temporary import license exemptions.

(a) * * *

(4) Has been rejected for permanent import by the Department of Justice and is being returned to the country from which it was shipped; or

* * * * *

■ 5. Section 123.9 is amended by revising paragraphs (b)(1) and (2) and adding paragraph (d) to read as follows:

§ 123.9 Country of ultimate destination and approval of reexports or retransfers.

* * * * *

(b) * * *

(1) The exporter must incorporate the following information as an integral part of the commercial invoice, whenever defense articles are to be shipped (exported in tangible form), retransferred (in tangible form), or reexported (in tangible form) pursuant to a license or other approval under this subchapter:

(i) The country of ultimate destination;

(ii) The end-user;

(iii) The license or other approval number or exemption citation; and

(iv) The following statement: "These items are controlled by the U.S. government and authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations."

Note to paragraph (b)(1)(iv): The phrase "or as otherwise authorized by U.S. law and regulations" is included because U.S. regulations contain specific exemptions from licensing requirements (*e.g.,* ITAR exemptions, and EAR license exceptions and No License Required designations) and allow for certain amounts of U.S. origin content in foreign made items (see 15 CFR 734).

(2) When exporting items subject to the EAR (see §§ 120.5, 120.42 and 123.1(b) of this subchapter) pursuant to a Department of State license or other approval, the U.S. exporter must also provide the end-user and consignees with the appropriate EAR classification information for each item. This includes the Export Control Classification Number (ECCN) or EAR99 designation.

* * * * *

(d) The Directorate of Defense Trade Controls may authorize reexport or retransfer of an item subject to the EAR provided that:

(1) The item was initially exported, reexported or transferred pursuant to a Department of State license or other approval;

(2) The item is for end-use in or with a defense article; and

(3) All requirements of paragraph (c) of this section are satisfied for the item subject to the EAR, as well as for the associated defense article.

* * * * *

■ 6. Revise § 123.13 to read as follows:

§ 123.13 Domestic aircraft shipments via a foreign country.

A license is not required for the shipment by air of a defense article from one location in the United States to another location in the United States via a foreign country.

PART 124—AGREEMENTS, OFF SHORE PROCUREMENT, AND OTHER DEFENSE SERVICES

■ 7. The authority citation for part 124 continues to read as follows:

Authority: Sec. 2, 38, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2797); 22 U.S.C. 2651a; 22 U.S.C. 2776; Pub. L. 105–261; Section 1261, Pub. L. 112–239; E.O. 13637, 78 FR 16129.

■ 8. Section 124.7 is amended by redesignating the introductory text as paragraph (a) introductory text, revising newly designated paragraph (a)(1), and adding reserved paragraph (b).

The revision reads as follows:

§ 124.7 Information required in all manufacturing license agreements and technical assistance agreements.

(a) * * *

(1) The agreement must describe the defense article to be manufactured and all defense articles to be exported, including any test and support equipment or advanced materials. They should be described by military nomenclature, contract number, National Stock Number, nameplate data, or other specific information. Only defense articles listed in the agreement will be eligible for export under the exemption in § 123.16(b)(1) of this subchapter.

* * * * *

§ 124.8 [Amended]

■ 9. Section 124.8 is amended by redesignating the introductory text as paragraph (a) introductory text and adding reserved paragraph (b).

■ 10. Section 124.9 is amended by revising paragraph (a)(6) to read as follows:

§ 124.9 Additional clauses required only in manufacturing license agreements.

(a) * * *

(6) (Licensee) agrees to incorporate the following statement as an integral provision of a contract, commercial invoice or other appropriate document whenever the licensed articles are sold or otherwise transferred:

These items are controlled by the U.S. government and authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations.

■ 11. Section 124.12 is amended by revising paragraph (a) introductory text and paragraph (b)(4) to read as follows:

§ 124.12 Required information in letters of transmittal.

(a) An application for the approval of a manufacturing license or technical assistance agreement with a foreign person must be accompanied by an explanatory letter. The explanatory letter shall contain:

* * * * *

(b) * * *

(4) "If this agreement grants any rights to sub-license, it will be amended to require that all sub-licensing arrangements incorporate all the provisions of the basic agreement that refer to the U.S. Government and the Department of State (*i.e.,* 22 CFR 124.8 and 124.9)."

■ 12. Section 124.14 is amended by revising paragraphs (c)(7) and (e) introductory text to read as follows:

§ 124.14 Exports to warehouses or distribution points outside the United States.

* * * * *

(c) * * *

(7) "(Licensee) agrees to incorporate the following statement as an integral provision of a contract, invoice or other appropriate document whenever the articles covered by this agreement are sold or otherwise transferred: 'These items are controlled by the U.S. government and authorized for export only to the country of ultimate destination for use by the ultimate consignee or end-user(s) herein identified. They may not be resold, transferred, or otherwise disposed of, to any other country or to any person other than the authorized ultimate consignee or end-user(s), either in their original form or after being incorporated into other items, without first obtaining approval from the U.S. government or as otherwise authorized by U.S. law and regulations.' "

* * * * *

(e) *Transmittal letters.* Requests for approval of warehousing and distribution agreements with foreign persons must be made by letter. The letter shall contain:

* * * * *

PART 125—LICENSES FOR THE EXPORT OF TECHNICAL DATA AND CLASSIFIED DEFENSE ARTICLES

■ 13. The authority citation for part 125 continues to read as follows:

Authority: Secs. 2 and 38, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778); 22 U.S.C. 2651a; E.O. 13637, 78 FR 16129.

■ 14. Section 125.2 is amended by revising paragraph (a) to read as follows:

§ 125.2 Exports of unclassified technical data.

(a) *License.* A license (DSP–5) is required for the export of unclassified technical data unless the export is exempt from the licensing requirements of this subchapter. In the case of a plant visit, details of the proposed discussions must be transmitted to the Directorate of Defense Trade Controls for an appraisal of the technical data.

* * * * *

■ 15. Section 125.7 is amended by revising paragraph (b) to read as follows:

§ 125.7 Procedures for the export of classified technical data and other classified defense articles.

* * * * *

(b) An application for the export of classified technical data or other classified defense articles must be accompanied by a completed form DSP–83 (*see* § 123.10 of this subchapter). All classified materials accompanying an application must be transmitted to the Directorate of Defense Trade Controls in accordance with the procedures contained in the Department of Defense National Industrial Security Program Operating Manual (unless such requirements are inconsistent with guidance provided by the Directorate of Defense Trade Controls, in which case the latter guidance must be followed).

PART 126—GENERAL POLICIES AND PROVISIONS

■ 16. The authority citation for part 126 continues to read as follows:

Authority: Secs. 2, 38, 40, 42, and 71, Pub. L. 90–629, 90 Stat. 744 (22 U.S.C. 2752, 2778, 2780, 2791, and 2797); 22 U.S.C. 2651a; 22 U.S.C. 287c; E.O. 12918, 59 FR 28205; 3 CFR, 1994 Comp., p. 899; Sec. 1225, Pub. L. 108–375; Sec. 7089, Pub. L. 111–117; Pub. L. 111–266; Section 7045, Pub. L. 112–74; Section 7046, Pub. L. 112–74; E.O. 13637, 78 FR 16129.

■ 17. Section 126.9 is amended by revising the heading and the first sentence of paragraph (a) and adding paragraph (c) to read as follows:

§ 126.9 Advisory opinions and related authorizations.

(a) Preliminary authorization determinations. A person may request information from the Directorate of Defense Trade Controls on whether it would likely grant a license or other approval for a particular defense article or defense service to a particular country. * * *

* * * * *

(c) *Interpretations of the ITAR.* Any person may request an interpretation of the requirements set forth in this subchapter in the form of an advisory opinion. A request for an advisory opinion must be made in writing. Any response to an advisory opinion provided by the Directorate of Defense Trade Controls pursuant to this paragraph shall not be an authorization to export and shall not bind the Department to grant or deny any such authorization.

Rose E. Gottemoeller,

Under Secretary, Arms Control and International Security, Department of State.

[FR Doc. 2016–19550 Filed 8–16–16; 8:45 am]

BILLING CODE 4710–25–P

DEPARTMENT OF DEFENSE

Department of the Navy

32 CFR Part 706

Certifications and Exemptions Under the International Regulations for Preventing Collisions at Sea, 1972

AGENCY: Department of the Navy, DoD.

ACTION: Final rule.

SUMMARY: The Department of the Navy (DoN) is amending its certifications and exemptions under the International Regulations for Preventing Collisions at Sea, 1972 (72 COLREGS), to reflect that the Deputy Assistant Judge Advocate General (DAJAG) (Admiralty and Maritime Law) has determined that USS GABRIELLE GIFFORDS (LCS 10) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with certain provisions of the 72 COLREGS without interfering with its special function as a naval ship. The intended effect of this rule is to warn mariners in waters where 72 COLREGS apply.

DATES: This rule is effective August 17, 2016 and is applicable beginning August 9, 2016.

FOR FURTHER INFORMATION CONTACT: Commander Theron R. Korsak, JAGC, U.S. Navy, Admiralty Attorney, (Admiralty and Maritime Law), Office of the Judge Advocate General, Department of the Navy, 1322 Patterson Ave. SE., Suite 3000, Washington Navy Yard, DC 20374–5066, telephone number: 202–685–5040.

SUPPLEMENTARY INFORMATION: Pursuant to the authority granted in 33 U.S.C. 1605, the DoN amends 32 CFR part 706.

This amendment provides notice that the DAJAG (Admiralty and Maritime Law), under authority delegated by the Secretary of the Navy, has certified that USS GABRIELLE GIFFORDS (LCS 10) is a vessel of the Navy which, due to its special construction and purpose, cannot fully comply with the following specific provisions of 72 COLREGS without interfering with its special function as a naval ship: Annex I paragraph 2(a)(i), pertaining to the height of the forward masthead light above the hull; Annex I, paragraph 2(f)(i), pertaining to the placement of the masthead light or lights above and clear of all other lights and obstructions; Annex I, paragraph 3(a), pertaining to the location of the forward masthead light in the forward quarter of the ship, and the horizontal distance between the forward and after masthead light; Annex I, paragraph 3(c), pertaining to the task light's horizontal distance from the fore and aft centerline of the vessel in the athwartship direction. The DAJAG (Admiralty and Maritime Law) has also certified that the lights involved are located in closest possible compliance with the applicable 72 COLREGS requirements.

Moreover, it has been determined, in accordance with 32 CFR parts 296 and 701, that publication of this amendment for public comment prior to adoption is impracticable, unnecessary, and contrary to public interest since it is based on technical findings that the placement of lights on this vessel in a manner differently from that prescribed herein will adversely affect the vessel's ability to perform its military functions.

List of Subjects in 32 CFR Part 706

Marine safety, Navigation (water), Vessels.

For the reasons set forth in the preamble, the DoN amends part 706 of title 32 of the Code of Federal Regulations as follows:

PART 706—CERTIFICATIONS AND EXEMPTIONS UNDER THE INTERNATIONAL REGULATIONS FOR PREVENTING COLLISIONS AT SEA, 1972

■ 1. The authority citation for part 706 continues to read as follows:

Authority: 33 U.S.C. 1605.

■ 2. Section 706.2 is amended by:

■ a. In Table One, adding, in alpha numerical order, by vessel number, an entry for USS GABRIELLE GIFFORDS (LCS 10);

■ b. In Table Four, under paragraph 15, adding, in alpha numerical order, by vessel number, an entry for USS GABRIELLE GIFFORDS (LCS 10);

■ c. In Table Four, under paragraph 16, adding, in alpha numerical order, by vessel number, an entry for USS GABRIELLE GIFFORDS (LCS 10); and

■ d. In Table Five, adding, in alpha numerical order, by vessel number, an entry for USS GABRIELLE GIFFORDS (LCS 10).

The additions read as follows:

§ 706.2 Certifications of the Secretary of the Navy under Executive Order 11964 and 33 U.S.C. 1605.

* * * * *

TABLE ONE

Vessel	No.	Distance in meters of forward masthead light below minimum required height § 2(a)(i) annex I
* * * * * * *		
USS GABRIELLE GIFFORDS	LCS 10	4.91
* * * * * * *		

* * * * *

15. * * *

TABLE FOUR

Vessel	No.	Horizontal distances from the fore and aft centerline of the vessel in the athwartship direction (meters)
* * * * * * *		
USS GABRIELLE GIFFORDS	LCS 10	Upper—0.16. Middle—1.2. Lower—1.2.

* * * * *

16. * * *

Vessel	No.	Obstruction angle relative ship's headings
* * * * * * *		
USS GABRIELLE GIFFORDS	LCS 10	71° thru 73°. 76° thru 78°. 287° thru 289°.
* * * * * * *		

* * * * *

TABLE FIVE

Vessel	No.	Masthead lights not over all other lights and obstructions; annex I, sec. 2(f)	Forward masthead light not in forward quarter of ship; annex I, sec. 3(a)	After masthead light less than 1/2 ship's length aft of forward masthead light, annex I, sec. 3(a)	Percentage horizontal separation attained
* * * * * * *					
USS GABRIELLE GIFFORDS	LCS 10		X	X	17.9

Approved: August 9, 2016.

C.J. Spain,

Deputy Assistant Judge Advocate General (Admiralty and Maritime Law), Acting.

Dated: August 11, 2016.

N.A. Hagerty-Ford,

Commander, Judge Advocate General's Corps, U.S. Navy, Federal Register Liaison Officer.

[FR Doc. 2016–19600 Filed 8–16–16; 8:45 am]

BILLING CODE 3810–FF–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[Docket No. USCG–2016–0797]

RIN 1625–AA08

Special Local Regulations; Tall Ships Duluth 2016 Parade of Sail, Lake Superior, Duluth, MN

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary special local regulations on the navigable waters of Lake Superior and Duluth Harbor, Minnesota for the Tall Ships Duluth 2016 Parade of Sail. This action is necessary to provide for the safety of life and property on the navigable waters of Lake Superior and Duluth, Minnesota, during Tall Ships Duluth 2016 Parade of Sail on August 18, 2016. These temporary special local regulations would restrict vessel traffic in portions of Lake Superior and Duluth Harbor, Minnesota, unless authorized by the Captain of the Port (COTP) Duluth.

DATES: This rule is effective from 9:00 a.m. through 5:00 p.m. August 18, 2016.

ADDRESSES: To view documents mentioned in this preamble as being available in the docket, go to *http://www.regulations.gov,* type USCG–2016–0797 in the "SEARCH" box and click "SEARCH." Click on Open Docket Folder on the line associated with this rule.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call or email Lieutenant Junior Grade John Mack, Waterways management, MSU Duluth, Coast Guard; telephone 218–725–3818, email *John.V.Mack@uscg.mil.*

SUPPLEMENTARY INFORMATION:

I. Table of Abbreviations

CFR	Code of Federal Regulations
DHS	Department of Homeland Security
FR	Federal Register
NPRM	Notice of proposed rulemaking
§	Section
U.S.C.	United States Code

II. Background Information and Regulatory History

The Coast Guard is issuing this temporary rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule because doing so would be impracticable. Amplifying information regarding event schedule, plan, and vessel participants was not provided by the event sponsor with sufficient time to accommodate the comment period prior to the August 18, 2016 event. Thus, delaying the effective date of this rule to wait for the comment period to run would be both impracticable because it would be impossible to have the rule implemented before the date of the event.

We are issuing this rule, and under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making it effective less than 30 days after publication in the **Federal Register**. Delaying the effective date of this rule would be contrary to public interest as it would inhibit the Coast Guard's ability to protect spectator and vessels from the hazards associated with the event.

III. Legal Authority and Need for Rule

The Coast Guard is issuing this rule under authority in 33 U.S.C. 1233. These temporary special local regulations will provide for the safety of life and protection of property on the navigable waters of Lake Superior and Duluth Harbor, Minnesota, by providing for the organized viewing of Tall Ships and preventing the large number of spectator vessels from interfering with the organized and controlled Parade of Sail.

IV. Discussion of the Rule

Duluth, Minnesota will host the Tall Ships Duluth 2016 from August 18–21, 2016. This visit of sailing vessels is part of a recurring series of sail training races, rallies, cruises, and port festivals organized by Tall Ships America in conjunction with host ports in the United States and Canada. The Tall Ships Duluth 2016, including a Parade of Sail, is akin to similar events held several times in the past in Duluth, Minnesota, the most recent being in 2013.

The Tall Ships visit to Duluth, which will occur from August 18–21, 2016, will include a Parade of Sail on August 18, 2016. About 9 vessels are expected to participate in the Parade of Sail. These temporary special local regulations will provide for the safety of life and protection of property on the navigable waters of Lake Superior and Duluth Harbor, Minnesota, by providing for the organized viewing of Tall Ships and by preventing the large number of spectator vessels from interfering with the organized and controlled Parade of Sail. There may be vessels participating in the event from several foreign countries and the high visibility of this event warrants that temporary special local regulations be established to ensure the safety of vessels and spectators from hazards associated with Tall Ships Duluth 2016.

The participating vessels will berth at assigned facilities in Duluth, Minnesota, from August 18–21, 2016. On August 19, 2016, visitors will be permitted to board the berthed vessels from shore. On the morning of August 22, 2016, the Tall Ships will depart the Duluth Harbor.

The Coast Guard believes that vessel congestion due to the large number of participating and spectator vessels may pose a significant hazard to navigation. To reduce the risk associated with congested waterways the Coast Guard is proposing to establish regulated areas to restrict vessel movement around the location of the participating Tall Ships while participating in the Parade of Sail in Duluth Harbor. These temporary special local regulations would be in effect from 9:00 a.m. through 5:00 p.m. August 18, 2016.

Area "Duluth Harbor": This Area includes all waters of Lake Superior and Duluth Harbor bounded by Rice's Point to the west and Duluth to the north, within the following boundaries: Beginning at position 46°49′11″ N., 92°02′20″ W., then due south to position 46°45′12″ N., 92°02′20″ W., and then west to position 46°45′12″ N., 92°05′40″ W. (Duluth Marine Terminal South Light (LLNR 15935)). This area is needed to protect the maritime public and participating vessels from hazards to navigation associated with numerous spectator craft during the Parade of Sail on August 18, 2016.

Area "Parade of Sail": This Area includes all waters of Lake Superior and Duluth Harbor bounded by Duluth to the north, within the following boundaries: Beginning at position 46°46′51.54″ N., 92°05′17.03″ W. (North Pier Light (LLNR 15855)), then northeast to position 46°47′18.96″ N., 92°4′0.84″ W., then south to position 46°47′11.04″ N., 92°03′55.08″ W., then southwest to position 46°46′48.46″ N., 92°05′15.02″ W. (South Breakwater Outer Light (LLNR 15845)), then to position 46°46′40.66″ N., 92°05′36.59″ W. near the Duluth Lift Bridge, then to position 46°46′34.04″ N., 92°05′39.64″ W. (Basin Buoy 1 (LLNR 15865)), and then west to position 46°46′36.42″ N., 92°06′07.86″ W. This area is needed to enhance navigation safety by facilitating the organized and controlled transit of participating vessels through the parade route and minimizing the impact on the maritime community.

V. Regulatory Analyses

We developed this rule after considering numerous statutes and Executive order related to rulemaking. Below we summarize our analyses based on a number of these statutes and Executive orders, and we discuss First Amendment rights of protestors.

A. Regulatory Planning and Review

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits. Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule has not been designated a "significant regulatory action," under Executive Order 12866. Accordingly, it has not been reviewed by the Office of Management and Budget.

This regulatory action determination is based on the size, location, duration, and time-of-year of the special local regulations. These proposed regulations involve only the Duluth portion of Duluth/Superior Harbor and would close the Duluth Entry Channel to commercial traffic only for several hours during the actual Parade of Sail on August 18, 2016. The Superior Entry would remain open to vessel traffic at all times. The impact of these proposed regulations will not be significant because these regulations would be in effect for only a portion of one day centered on the Parade of Sail, and most vessel traffic can pass safely around affected areas of Duluth Harbor by transiting through the Superior Entry.

Notice of these special local regulations will be provided prior to the event through Local Notice to Mariners and Broadcast Notice to Mariners. In addition, the sponsoring organization, Draw Events, LLC., is planning to publish information of the event in local newspapers, pamphlets, and Internet sites.

B. Impact on Small Entities

The Regulatory Flexibility Act of 1980, 5 U.S.C. 601–612, as amended, requires Federal agencies to consider the potential impact of regulations on small entities during rulemaking. The term "small entities" comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000. The Coast Guard certifies under 5 U.S.C. 605(b) that this rule will not have a significant economic impact on a substantial number of small entities.

While some owners or operators of vessels intending to transit the regulated areas may be small entities, for the reasons stated in section V.A above, this rule will not have a significant economic impact on any vessel owner or operator.

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Public Law 104–121), we want to assist small entities in understanding this rule. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency's responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

C. Collection of Information

This rule will not call for a new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

D. Federalism and Indian Tribal Governments

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. We have analyzed this rule under that Order and have determined that it is consistent with the fundamental federalism principles and preemption requirements described in Executive Order 13132.

Also, this rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. If you believe this rule has implications for federalism or Indian tribes, please contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section above.

E. Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of $100,000,000 (adjusted for inflation) or more in any one year. Though this rule will not result in such an expenditure, we do discuss the effects of this rule elsewhere in this preamble.

F. Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023–01 and Commandant Instruction M16475.lD, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (42 U.S.C. 4321–4370f), and have determined that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule involves special local regulations lasting no more than 12 hours. It is categorically excluded from further review under paragraph 34(h) of Figure 2–1 of the Commandant Instruction. An environmental analysis checklist supporting this determination and a Categorical Exclusion

Determination are available in the docket where indicated under **ADDRESSES**. We seek any comments or information that may lead to the discovery of a significant environmental impact from this rule.

G. Protest Activities

The Coast Guard respects the First Amendment rights of protesters. Protesters are asked to contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section to coordinate protest activities so that your message can be received without jeopardizing the safety or security of people, places or vessels.

List of Subjects in 33 CFR Part 100

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 100 as follows:

PART 100—SAFETY OF LIFE ON NAVIGABLE WATERS

■ 1. The authority citation for Part 100 continues to read as follows:

Authority: 33 U.S.C. 1233.

■ 2. Add § 100.T09–0797 to read as follows:

§ 100.T09–0797 Special Local Regulations; Tall Ships Duluth 2016 Parade of Sail, Duluth, MN.

(a) *Regulated Areas.* (1) Area Duluth Harbor: This Area includes all waters of Lake Superior and Duluth Harbor bounded by Rice's Point to the west and Duluth to the north, within the following boundaries: Beginning at position 46°49′11″ N., 92°02′20″ W., then due south to position 46°45′12″ N., 92°02′20″ W., and then west to position 46°45′12″ N., 92°05′40″ W. (Duluth Marine Terminal South Light (LLNR 15935)).

(2) Area Parade of Sail: This Area includes all waters of Lake Superior and Duluth Harbor bounded by Duluth to the north, within the following boundaries: Beginning at position 46°46′51.54″ N., 92°05′17.03″ W. (North Pier Light (LLNR 15855)), then northeast to position 46°47′18.96″ N., 92°4′0.84″ W., then south to position 46°47′11.04″ N., 92°03′55.08″ W., then southwest to position 46°46′48.46″ N., 92°05′15.02″ W. (South Breakwater Outer Light (LLNR 15845)), then to position 46°46′40.66″ N., 92°05′36.59″ W. near the Duluth Lift Bridge, then to position 46°46′34.04″ N., 92°05′39.64″ W. (Basin Buoy 1 (LLNR 15865)), and then west to position 46°46′36.42″ N., 92°06′07.86″ W.

(b) *Special Local Regulations.* (1) In accordance with the general regulations in § 100.35 of this part, entry into, transiting, or anchoring within the regulated areas is prohibited unless designated for vessels of that type or entry is authorized by the Captain of the Port (COTP) Duluth or on-scene representatives.

(2) All persons and vessels are authorized by the COTP Duluth to enter areas of these special local regulations in accordance with the following restrictions:

(i) Area Duluth Harbor: Vessels transiting this Area must do so at a speed of not more than six (6) knots or at no wake speed, whichever is less. Vessels proceeding under sail will not be allowed in this Area unless also propelled by machinery, due to limited maneuvering ability around numerous other spectator craft viewing the Tall Ships.

(ii) Area Parade of Sail: This Area will be closed to all vessel traffic, except those vessels designated as participants.

(3) The Coast Guard will provide notice of the regulated areas prior to the event through Local Notice to Mariners and Broadcast Notice to Mariners. Notice will also be provided by on-scene representatives.

(4) The "on-scene representative" of the Captain of the Port is any Coast Guard commissioned, warrant, or petty officer and any Federal, State, or local officer designated by the Captain of the Port to act on his behalf.

(5) Vessel operators desiring to enter or operate within the regulated areas shall contact the Captain of the Port Duluth by telephone at 218–725–3818, or on-scene representative via VHF radio on channel 16, to obtain permission to do so. Vessel operators given permission to enter, operate, transit through, anchor in, or remain within the regulated areas must comply with all instructions given by COTP Duluth or on-scene representatives.

Dated: August 12, 2016.

E.E. Williams,

Commander, U.S. Coast Guard, Captain of the Port Duluth.

[FR Doc. 2016–19652 Filed 8–16–16; 8:45 am]

BILLING CODE 9110–04–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–0778]

Drawbridge Operation Regulation; Rockaway Inlet, Queens, NY

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Marine Parkway Bridge across the Rockaway Inlet, mile 3.0, at Queens, New York. This deviation is necessary to allow the bridge owner to replace mechanical and electrical components for the lift span operation.

DATES: This deviation is effective from 7 a.m. on November 15, 2016 to 5 p.m. on May 13, 2017.

ADDRESSES: The docket for this deviation, [USCG–2016–0778] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Judy Leung-Yee, Project Officer, First Coast Guard District, telephone (212) 514–4330, email *judy.k.leung-yee@uscg.mil.*

SUPPLEMENTARY INFORMATION:

The Marine Parkway Bridge, mile 3.0, across the Rockaway Inlet, has a vertical clearance in the closed position of 55 feet at mean high water and 59 feet at mean low water. The existing bridge operating regulations are found at 33 CFR 117.795(a).

The waterway is transited by commercial barge traffic of various sizes.

The bridge owner, MTA Bridges and Tunnels, requested a temporary deviation from the normal operating schedule to replace mechanical and electrical components for the lift span operation.

Under this temporary deviation, the Marine Parkway Bridge shall remain in the closed position from 7 a.m. on November 15, 2016 to 5 p.m. May 13, 2017.

Vessels able to pass under the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass.

The Coast Guard will inform the users of the waterways through our Local Notice and Broadcast to Mariners of the change in operating schedule for the bridge so that vessel operations can arrange their transits to minimize any impact caused by the temporary deviation. The Coast Guard notified various companies of the commercial oil and barge vessels and they have no objections to the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: August 11, 2016.

C.J. Bisignano,

Supervisory Bridge Management Specialist, First Coast Guard District.

[FR Doc. 2016–19535 Filed 8–16–16; 8:45 am]

BILLING CODE 9110–04–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R03–OAR–2016–0189; FRL–9950–69–Region 3]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Control of Volatile Organic Compound Emissions From Fiberglass Boat Manufacturing Materials

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is approving a revision to the Pennsylvania state implementation plan (SIP) submitted by the Commonwealth of Pennsylvania. This SIP revision pertains to Pennsylvania's regulation for fiberglass boat manufacturing materials found in section 129.74 of the Pennsylvania Code. This regulation meets the requirement to adopt reasonably available control technology (RACT) for sources covered by EPA's control techniques guidelines (CTG) standards for fiberglass boat manufacturing materials. EPA is, therefore, approving this revision to the Pennsylvania SIP in accordance with the requirements of the Clean Air Act (CAA).

DATES: This final rule is effective on September 16, 2016.

ADDRESSES: EPA has established a docket for this action under Docket ID Number EPA–R03–OAR–2016–0189. All documents in the docket are listed on the *http://www.regulations.gov* Web site. Although listed in the electronic docket, some information is not publicly available, *i.e.,* confidential business information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available through *http://www.regulations.gov,* or please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section for additional availability information.

FOR FURTHER INFORMATION CONTACT: Irene Shandruk, (215) 814–2166, or by email at *shandruk.irene@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 172(c)(1) of the CAA provides that SIPs for nonattainment areas must include reasonably available control measures (RACM), including RACT, for sources of emissions. Section 182(b)(2)(A) provides that for certain nonattainment areas, states must revise their SIPs to include RACT for sources of volatile organic compound (VOC) emissions covered by a CTG document issued after November 15, 1990 and prior to the area's date of attainment. Furthermore, pursuant to section 184(b)(1)(B) of the CAA, all areas in the Ozone Transport Region (OTR), such as Pennsylvania, must submit SIP revisions that include implementation of RACT with respect to all sources of VOCs in the states covered by a CTG. EPA defines RACT as "the lowest emission limitation that a particular source is capable of meeting by the application of control technology that is reasonably available considering technological and economic feasibility." 44 FR 53761 (September 17, 1979).

CTGs are intended to provide state and local air pollution control authorities information that should assist them in determining RACT for VOCs from various sources. The CTG for fiberglass boat manufacturing materials (Publication No. EPA 453/R–08–004; September 2008) provides control recommendations for reducing VOC emissions from the use of gel coats, resins, and materials used to clean application equipment in fiberglass boat manufacturing operations. This CTG applies to facilities that manufacture hulls or decks of boats from fiberglass, or build molds to make fiberglass boat hulls or decks. EPA's 2008 CTG recommends that the following operations should be covered: Open molding resin and gel coat operations (these include pigmented gel coat, clear gel coat, production resin, tooling gel coat, and tooling resin); resin and gel coat mixing operations; and resin and gel coat application equipment cleaning operations.

EPA's 2008 CTG recommends the following VOC reduction measures: VOC emission limits for molding resins and gel coats; work practices for resin and gel coat mixing containers; and VOC content and vapor pressure limits for cleaning materials. Recommended VOC emission limits for open molding resin and gel coat operations are shown in Table 1. A more detailed explanation for determining the VOC emission limits for molding resin and gel coats can be found in the Technical Support Document (TSD) for this rulemaking under Docket ID Number EPA–R03–OAR–2016–0189 and available online at *http://www.regulations.gov.*

TABLE 1—MONOMER VOC CONTENT LIMITATIONS FOR OPEN MOLDING RESIN AND GEL COAT OPERATIONS

Materials	Application method	Individual monomer VOC content or weight average monomer VOC content limit (weight percent)
Production Resin	Atomized (spray)	28
Production Resin	Nonatomized	35
Pigmented Gel Coat	Any Method	33
Clear Gel Coat	Any Method	48
Tooling Resin	Atomized	30
Tooling Resin	Nonatomized	39
Tooling Gel Coat	Any Method	40

II. Summary of SIP Revision

On March 2, 2016, the Pennsylvania Department of Environmental Protection (PADEP) submitted to EPA a SIP revision concerning implementation of RACT requirements for the control of VOC emissions from fiberglass boat manufacturing materials. Pennsylvania is adopting EPA's CTG standards for fiberglass boat manufacturing materials, including the emission limits found in Table 1. The regulation is contained in 25 *Pa. Code* Chapter 129 (relating to standards for sources), and this SIP revision seeks to add 25 *Pa. Code* section 129.74 (control of VOC emissions from fiberglass boat manufacturing materials) to the Pennsylvania SIP. EPA finds the provisions in 25 *Pa. Code* section 129.74 identical to the CTG standards for fiberglass boat manufacturing materials and is therefore approvable in accordance with sections 172(c)(1), 182(b)(2)(A), and 184(b)(1)(B) of the CAA.

On May 20, 2016 (81 FR 31885), EPA published a notice of proposed rulemaking (NPR) proposing to approve Pennsylvania's March 2, 2016 SIP revision. Other specific requirements and the rationale for EPA's approval action are explained in the NPR and TSD under Docket ID Number EPA–R03–OAR–2016–0189 and will not be restated here. No public comments were received on the NPR.

III. Final Action

EPA is approving the March 2, 2016 Pennsylvania SIP revision concerning the addition of 25 *Pa. Code* section 129.74 to the Pennsylvania SIP because section 129.74 meets the requirement to adopt RACT for sources covered by EPA's CTG standards for fiberglass boat manufacturing materials.

IV. Incorporation by Reference

In this rulemaking action, EPA is finalizing regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is finalizing the incorporation by reference of the Pennsylvania rule discussed in section II of this preamble. Therefore, these materials have been approved by EPA for inclusion in the SIP, have been incorporated by reference by EPA into that plan, are fully federally enforceable under sections 110 and 113 of the CAA as of the effective date of the final rulemaking of EPA's approval, and will be incorporated by reference by the Director of the Federal Register in the next update to the SIP compilation.[1] EPA has made, and will continue to make, these materials generally available through *http://www.regulations.gov* and/or at the EPA Region III Office (please contact the person identified in the "For Further Information Contact" section of this preamble for more information).

V. Statutory and Executive Order Reviews

A. General Requirements

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the CAA and applicable federal regulations. 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this action merely approves state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Publ. L. 104–4);
- does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, this rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), because the SIP is not approved to apply in Indian country located in the state, and EPA notes that it will not impose substantial direct costs on tribal governments or preempt tribal law.

B. Submission to Congress and the Comptroller General

The Congressional Review Act, 5 U.S.C. 801 *et seq.,* as added by the Small Business Regulatory Enforcement Fairness Act of 1996, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report, which includes a copy of the rule, to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this action and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. A major rule cannot take effect until 60 days after it is published in the **Federal Register**. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

C. Petitions for Judicial Review

Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by October 17, 2016. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action.

This action concerning Pennsylvania's control of VOC emissions from fiberglass boat manufacturing materials may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Ozone, Volatile organic compounds.

Dated: August 2, 2016.

Shawn M. Garvin,

Regional Administrator, Region III.

40 CFR part 52 is amended as follows:

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[1] 62 FR 27968 (May 22, 1997).

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart NN—Pennsylvania

■ 2. In § 52.2020, the table in paragraph (c)(1) is amended by adding an entry for "Section 129.74" in numerical order to read as follows:

§ 52.2020 Identification of plan.

* * * * *

(c) * * *

(1) * * *

State citation	Title/subject	State effective date	EPA approval date	Additional explanation/ § 52.2063 citation
Title 25—Environmental Protection Article III—Air Resources				
* * * * * * *				
Section 129.74	Control of VOC emissions from fiberglass boat manufacturing materials.	12/19/15	8/17/16 [*Insert* ***Federal Register*** *citation*].	New section is added; the requirements of section 129.74 supersede the requirements of a RACT permit issued under sections 129.91–95 prior to December 19, 2015, to the owner or operator of a source subject to section 129.74 to control, reduce or minimize VOCs from a fiberglass boat manufacturing process, except to the extent the RACT permit contains more stringent requirements.
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[FR Doc. 2016–19540 Filed 8–16–16; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 648

[Docket No. 160301164–6694–02]

RIN 0648–BF87

Fisheries of the Northeastern United States; Northeast Skate Complex Fishery; Framework Adjustment 3 and 2016–2017 Specifications

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Final rule.

SUMMARY: This rule approves regulations to implement Northeast Skate Complex Fishery Management Plan Framework Adjustment 3 management measures, including fishing year 2016–2017 specifications, and implements a new seasonal quota allocation for the skate wing fishery. This rule is necessary because it updates the Skate Fishery Management Plan to be consistent with the most recent scientific information and it improves management of the skate fisheries. The intended effect of this rule is to help conserve skate stocks while maintaining economic opportunities for the skate fisheries.

DATES: Effective on August 17, 2016.

ADDRESSES: Copies of Framework 3, including the Environmental Assessment and Regulatory Impact Review (EA/RIR), and other supporting documents for the action are available from Thomas A. Nies, Executive Director, New England Fishery Management Council, 50 Water Street, Mill 2, Newburyport, MA 01950. The framework is also accessible via the Internet at: *http://www.greateratlantic.fisheries.noaa.gov.*

FOR FURTHER INFORMATION CONTACT: William Whitmore, Fishery Policy Analyst, (978) 281–9182.

SUPPLEMENTARY INFORMATION:

Background

Approved Measures

On June 6, 2016, we proposed in the **Federal Register** (81 FR 36251) management modifications to implement Framework Adjustment 3 to the Northeast Skate Complex Fishery Management (FMP), which includes catch specifications for fishing years 2016–2017. After reviewing public comments in response to the proposed rule, we are approving Framework 3 and the 2016–2017 specifications as detailed in our proposed rule.

Specifications for Fishing Years 2016–2017

Specifications including the acceptable biological catch (ABC), annual catch limit (ACL), annual catch target (ACT), and total allowable landings (TALs) for the skate wing and bait fisheries, as well as possession limits, may be specified for up to 2 years. The 2016–2017 skate complex ABC and ACL is 31,081 metric tons (mt). After removing management uncertainty from the ABC, the ACT that remains is 23,311 mt. After removing discards and state landings from the ACT, the TAL that remains is 12,872 mt. Tables 1 and 2 (below) detail TALs and possession limits for the skate wing and skate bait fisheries—there are no possession limit changes from last year. These specifications and possession limits remain in effect until they are replaced.

TABLE 1—TOTAL ALLOWABLE LANDINGS FOR FISHING YEARS 2016–2017

Total Allowable Landings (TAL)	mt
Skate Wing Fishery:	
Season 1 (May 1–Aug 31)	4,722
Season 2 (Sept 1–Apr 30)	3,600

TABLE 1—TOTAL ALLOWABLE LANDINGS FOR FISHING YEARS 2016–2017—Continued

Total Allowable Landings (TAL)	mt
Skate Bait Fishery:	
Season 1 (May 1–Jul 31)	1,299
Season 2 (Aug 1–Oct 31)	1,565
Season 3 (Nov 1–Apr 30)	1,354

TABLE 2—POSSESSION LIMITS FOR FISHING YEARS 2016–2017

Skate possession limits *	Trip limits		
	Skate wings	Whole skates	Whole skate w/bait letter of authorization
NE Multispecies, Scallop, or Monkfish Day-At-Sea (DAS):			
Season 1 (May 1–Aug 31)	2,600 lb *1,179 kg*	5,902 lb *2,677 kg*	25,000 lb. *11,340 kg.*
Season 2 (Sept 1–Apr 30)	4,100 lb *1,860 kg*	9,306 lb *4,221 kg.*	
NE Multispecies B DAS:			
May 1–Apr 30	220 lb *100 kg*	500 lb *227 kg*	500 lb. *227 kg.*
Non-DAS:			
May 1–Apr 30	500 lb *227 kg*	1,135 lb *515 kg*	1,135 lb. *515 kg.*

* Possession limits may be modified in-season in order to prevent catch from exceeding quotas.

Skate Wing Adjustment Measures

Framework 3 modifies the skate wing TAL so that 57 percent of the skate wing TAL is allocated in Season 1 (May 1–August 31) with the remainder allocated in Season 2 (September 1–April 30). This modification was made because skate fishing effort is higher earlier in the fishing year and a seasonal apportionment with in-season change authority should ensure year-round fishing opportunities. Any portion of the Season 1 TAL that is unused is rolled over into Season 2. From May 1 through August 17, the Regional Administrator is required to reduce the directed skate wing possession limit for vessels fishing under a day-at-sea (DAS) from 2,600 lb (1,179 kg) to an incidental catch level of 500 lb (227 kg) when the fishery is projected to land 85 percent of its Season 1 quota. However, if harvest levels are projected to reach 85 percent sometime between August 18 and August 31 (the last two weeks of Season 1), the Regional Administrator maintains discretion on whether or not to reduce the directed possession limit. This option is included because it is difficult and sometimes impracticable for the agency to rapidly close a fishery immediately prior to the end of a season.

The DAS possession limit increases to 4,100 lb (1,860 kg) at the start of Season 2 (September 1) with the remainder of the annual skate wing TAL available in Season 2. In Season 2, the Regional Administrator may reduce the possession limit to 500 lb (227 kg) when 85 percent of the annual skate wing TAL is projected to have been landed, consistent with previous regulations. These in-season possession limit reductions are designed to mitigate the potential for prolonged closures for the directed skate fishery while still allowing some incidental catches to be landed.

Comments and Responses on Measures Proposed in Framework 3

We received four public comments on the proposed rule, including submissions on behalf of the Cape Cod Commercial Fishermen's Alliance and Shark Advocates International.

Comment 1: The Cape Cod Commercial Fishermen's Alliance and Shark Advocates International support the proposed seasonal specifications and possession limits.

Response 1: We are approving Framework 3 and the accompanying specifications and possession limits because these measures promote optimum yield, fishery conservation, and are based upon the best available science.

Comment 2: One commenter argued for a dramatic increase in quota while one commenter contended a dramatic decrease in quota is needed.

Response 2: The ABC, ACL, and TAL are based on the best available science with advice from the Council's Scientific and Statistical Committee. Therefore, we are approving this action because it is based on the best available science consistent with National Standard 2 of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) and with the Council recommendation. The proposed rule (81 FR 36251, June 6, 2016) details the justifications for modifying the specifications. These specifications are expected to result in optimum yield while ensuring that the stocks are not overfished or subject to overfishing (except for thorny skate, which is a prohibited species), consistent with National Standard 1 of the Magnuson-Stevens Act.

Comment 3: Shark Advocates International urged us to elevate the priority of examining and addressing the severe depletion of thorny skates.

Response 3: Although this comment does not directly apply to Framework 3, we are concerned with the stock status of thorny skates. In May 2015, we received a petition to list thorny skates as threatened or endangered. We found that the petition to list thorny skate presented substantial scientific or commercial information indicating that the petitioned action may be warranted and solicited information from the public that could be included in a candidate species status review (80 FR 65175, October 26, 2015). A thorny skate status review occurred on May 19, 2016, in Gloucester, MA. A report from the review is currently being developed and will undergo peer-review prior to being shared with the public.

Comment 4: The Cape Cod Commercial Fishermen's Alliance offered support for the Council's decision to further pursue limited access for the skate fishery.

Response 4: The Council has prioritized consideration of limiting access to the skate fishery. We will continue working with the Council so that it can research, review, and address its management priorities.

Changes From the Proposed Rule

After further review of the regulatory text deemed by the Council and included in the proposed rule, we are revising the regulatory language previously proposed at § 648.322(b)(2) to be consistent with the Regional Administrator's discretion to reduce the Season 2 skate-wing possession limit as provided in Framework Adjustment 1 to the FMP (76 FR 28328; May 17, 2011). These regulatory language changes do not alter the management measures specified in the proposed rule and are consistent with the intent of Framework 3.

Classification

The Administrator, Greater Atlantic Region, NMFS, determined that Framework 3 to the FMP is necessary for the conservation and management of the northeast skate complex and that it is consistent with the Magnuson-Stevens Fishery Conservation and Management Act and other applicable laws.

There is good cause under 5 U.S.C. 553(d)(3) to waive the 30-day delay in effective date. This final rule reduces TALs which are administered through different fishing seasons. Season 1 for the skate wing fishery began on May 1 and ends on August 31. It is possible that the fishery could approach a seasonal landing limit which would require possession limits to be reduced to avoid overharvesting. Waiving the 30-day implementation delay is necessary to ensure timely implementation of the reduced catch limits. Retaining a 30-day delay in implementation would be contrary to the public interest because it could result in a catch limit being exceeded. Immediate implementation of the new TALs, including the new seasonal measures, will benefit fishermen by helping to prevent overages and potentially providing fishing opportunities more evenly throughout the fishing year. For these reasons, NMFS finds it both contrary to the public interest and unnecessary to provide a 30-day delay in implementation.

This final rule has been determined to be not significant for the purpose of E.O. 12866.

A final regulatory flexibility analysis (FRFA) was prepared. The FRFA incorporates the initial regulatory flexibility analysis (IRFA), a summary of the significant issues raised by the public comments in response to the IRFA, and NMFS responses to those comments. A copy of this analysis is available from the Council [or NMFS] (see **ADDRESSES**).

A Summary of the Significant Issues Raised by the Public in Response to the IRFA, a Summary of the Agency's Assessment of Such Issues, and a Statement of Any Changes Made in the Final Rule as a Result of Such Comments

A description of the action, why it is being considered, and the legal basis were contained in the preamble of the proposed rule (81 FR 36251, June 6, 2016) and are not repeated here. The public did not provide any comments on the IRFA; therefore, there are no changes made in this final rule with regards to the economic analyses and impacts.

Description and Estimate of Number of Small Entities To Which the Rule Would Apply

This final rule would impact fishing vessels, including commercial fishing entities. In 2014, there were 2,012 vessels that held an open access skate permit. However, only 431 of those permit holders were active participants in the commercial skate fishery (*i.e.*, landed any amount of skates). Because there are several ownership affiliate groups (as explained in greater detail in the proposed rule) there are actually 364 active vessels in the skate fishery, only 3 of which qualified as large businesses.

On December 29, 2015, NMFS issued a final rule establishing a small business size standard of $11 million in annual gross receipts for all businesses primarily engaged in the commercial fishing industry (NAICS 11411) for Regulatory Flexibility Act (RFA) compliance purposes only (80 FR 81194, December 29, 2015). The $11 million standard became effective on July 1, 2016, and is to be used in place of the U.S. Small Business Administration's (SBA) previous standards of $20.5 million, $5.5 million, and $7.5 million for the finfish (NAICS 114111), shellfish (NAICS 114112), and other marine fishing (NAICS 114119) sectors, respectively, of the U.S. commercial fishing industry.

An IRFA was developed for this regulatory action prior to July 1, 2016, using SBA's previous size standards. Under the SBA's size standards, 3 of 364 skate fishing entities were determined to be large. NMFS has qualitatively reviewed the analyses prepared for this action using the new size standard. The new standard could result in a few more commercial shellfish businesses being considered small (due to the increase in small business size standards). In addition, the new standard could result in fewer commercial finfish businesses being considered small (due to the decrease in size standards). Skates are only responsible for a small fraction of total landings and revenue for any of these vessels so it is unlikely that these size-standard changes would have any impact on the previously conducted analyses.

Description of the Projected Reporting, Record-Keeping, and Other Compliance Requirements of This Final Rule

This final rule does not introduce any new reporting, recordkeeping, or other compliance requirements.

Description of the Steps the Agency Has Taken To Minimize the Significant Economic Impact on Small Entities Consistent With the Stated Objectives of Applicable Statutes

The ACL alternative described in the preambles of the proposed rule and this rule represents an ACL reduction in comparison to previous years' ACLs (maintaining the status quo measures). However, we do not anticipate any significant economic impacts on small entities to result from this action. While there is an overall reduction in the TAL, Framework 3 analyses indicate that actual skate landings in recent years have been close to the TAL we are approving for fishing years 2016–2017. This suggests that it is unlikely that potential revenue losses would be directly commensurate with the TAL reduction. By contrast, maintaining the status quo ACL is inconsistent with the stated objectives because it does not represent the best available science or the goals and objectives of the FMP. The seasonal allocation for the skate-wing fishery effected by this rule was developed to coincide with fishing effort so that more quota is allocated during the months when there is greater fishing effort. This is expected to reduce the risk of the fishery approaching a seasonal quota and having its possession limits reduced. The Council considered reducing the skate-wing possession limits due to the reduced TAL but elected to keep the status quo possession limits to further mitigate economic impacts from the ACL reductions. For these reasons, we do not expect revenues to be significantly impacted.

Section 212 of the Small Business Regulatory Enforcement Fairness Act of 1996 states that, for each rule or group of related rules for which an agency is required to prepare a FRFA, the agency shall publish one or more guides to assist small entities in complying with the rule, and shall designate such publications as "small entity compliance guides." The agency shall explain the actions a small entity is required to take to comply with a rule or group of rules. As part of this rulemaking process, a letter to permit holders that also serves as small entity compliance guide was prepared. Copies of this final rule are available from the Greater Atlantic Regional Fisheries Office (GARFO), and the compliance guide, *i.e.*, permit holder letter, will be sent to all holders of permits for the skate fishery. The guide and this final rule will be posted or publically available on the GARFO Web site.

List of Subjects in 50 CFR Part 648

Fisheries, Fishing, Reporting and recordkeeping requirements.

Dated: August 11, 2016.

Paul Doremus,

Deputy Assistant Administrator for Operations, National Marine Fisheries Service.

For the reasons set out in the preamble, NMFS amends 50 CFR part 648 as follows:

PART 648—FISHERIES OF THE NORTHEASTERN UNITED STATES

■ 1. The authority citation for part 648 continues to read as follows:

Authority: 16 U.S.C. 1801 *et seq.*

■ 2. In § 648.322, revise paragraphs (a)(1) and (b)(2) to read as follows:

§ 648.322 Skate allocation, possession, and landing provisions.

(a) * * *

(1) A total of 66.5 percent of the annual skate complex TAL shall be allocated to the skate wing fishery. All skate products that are landed in wing form, for the skate wing market, or classified by Federal dealers as food as required under § 648.7(a)(1)(i), shall count against the skate wing fishery TAL. The annual skate wing fishery TAL shall be allocated in two seasonal quota periods as follows:

(i) Season 1—May 1 through August 31, 57 percent of the annual skate wing fishery TAL shall be allocated;

(ii) Season 2—September 1 through April 30, the remainder of the annual skate wing fishery TAL not landed in Season 1 shall be allocated.

* * * * *

(b) * * *

(2) *In-season adjustment of skate wing possession limits.* The Regional Administrator has the authority, through a notice in the **Federal Register** consistent with the Administrative Procedure Act, to reduce the skate wing possession limit to 500 lb (227 kg) of skate wings (1,135 lb (515 kg) whole weight or any prorated combination of the allowable landing forms defined at paragraph (b)(4) of this section) for the remainder of the applicable quota season, under the following circumstances:

(i) When 85 percent of the Season 1 skate wing quota is projected to be landed between May 1 and August 17, the Regional Administrator shall reduce the skate wing possession limit to the incidental level described in paragraph (b)(2) of this section.

(ii) When 85 percent of the Season 1 skate wing quota is projected to be landed between August 18 and August 31, the Regional Administrator may reduce the skate wing possession limit to the incidental level described in paragraph (b)(2) of this section.

(iii) When 85 percent of the annual skate wing fishery TAL is projected to be landed in Season 2, the Regional Administrator may reduce the skate wing possession limit to the incidental level described in this paragraph, unless such a reduction would be expected to prevent attainment of the annual TAL.

* * * * *

[FR Doc. 2016–19601 Filed 8–16–16; 8:45 am]

BILLING CODE 3510–22–P

Proposed Rules

Federal Register
Vol. 81, No. 159
Wednesday, August 17, 2016

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 906

[Doc. No. AMS–SC–16–0059; SC16–906–2 PR]

Oranges and Grapefruit Grown in Lower Rio Grande Valley in Texas; Increased Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would implement a recommendation from the Texas Valley Citrus Committee (Committee) to increase the assessment rate established for the 2016–17 and subsequent fiscal periods from $0.08 to $0.09 per 7/10-bushel carton or equivalent of oranges and grapefruit handled under the marketing order (order). The Committee locally administers the order and is comprised of producers and handlers of oranges and grapefruit operating within the area of production. Assessments upon orange and grapefruit handlers are used by the Committee to fund reasonable and necessary expenses of the program. The fiscal period begins August 1 and ends July 31. The assessment rate would remain in effect indefinitely unless modified, suspended, or terminated.

DATES: Comments must be received by September 16, 2016.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed rule. Comments must be sent to the Docket Clerk, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Fax: (202) 720–8938; or Internet: *http://www.regulations.gov.* Comments should reference the document number and the date and page number of this issue of the **Federal Register** and will be available for public inspection in the Office of the Docket Clerk during regular business hours, or can be viewed at: *http://www.regulations.gov.* All comments submitted in response to this proposed rule will be included in the record and will be made available to the public. Please be advised that the identity of the individuals or entities submitting the comments will be made public on the internet at the address provided above.

FOR FURTHER INFORMATION CONTACT: Doris Jamieson, Marketing Specialist, or Christian D. Nissen, Regional Director, Southeast Marketing Field Office, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA; Telephone: (863) 324–3375, Fax: (863) 291–8614, or Email: *Doris.Jamieson@ams.usda.gov* or *Christian.Nissen@ams.usda.gov.*

Small businesses may request information on complying with this regulation by contacting Richard Lower, Marketing Order and Agreement Division, Specialty Crops Program, AMS, USDA, 1400 Independence Avenue SW., STOP 0237, Washington, DC 20250–0237; Telephone: (202) 720–2491, Fax: (202) 720–8938, or Email: *Richard.Lower@ams.usda.gov.*

SUPPLEMENTARY INFORMATION: This proposed rule is issued under Marketing Agreement and Order No. 906, as amended (7 CFR part 906), regulating the handling of oranges and grapefruit grown in the Lower Rio Grande Valley in Texas, hereinafter referred to as the "order." The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the "Act."

The Department of Agriculture (USDA) is issuing this proposed rule in conformance with Executive Orders 12866, 13563, and 13175.

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. Under the marketing order now in effect, orange and grapefruit handlers are subject to assessments. Funds to administer the order are derived from such assessments. It is intended that the assessment rate as proposed herein would be applicable to all assessable oranges and grapefruit beginning on August 1, 2016, and continue until amended, suspended, or terminated.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with USDA a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. Such handler is afforded the opportunity for a hearing on the petition. After the hearing, USDA would rule on the petition. The Act provides that the district court of the United States in any district in which the handler is an inhabitant, or has his or her principal place of business, has jurisdiction to review USDA's ruling on the petition, provided an action is filed not later than 20 days after the date of the entry of the ruling.

This proposed rule would increase the assessment rate established for the Committee for the 2016–17 and subsequent fiscal periods from $0.08 to $0.09 per 7/10-bushel carton or equivalent of oranges and grapefruit.

The Texas orange and grapefruit marketing order provides authority for the Committee, with the approval of USDA, to formulate an annual budget of expenses and collect assessments from handlers to administer the program. The members of the Committee are producers and handlers of Texas oranges and grapefruit. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget and assessment rate. The assessment rate is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

For the 2015–16 and subsequent fiscal periods, the Committee recommended, and USDA approved, an assessment rate that would continue in effect from fiscal period to fiscal period unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other information available to USDA.

The Committee met on June 2, 2016, and unanimously recommended 2016–17 expenditures of $751,148 and an assessment rate of $0.09 per 7/10-bushel carton or equivalent of oranges and grapefruit. In comparison, last year's budgeted expenditures were $701,148. The assessment rate of $0.09 is $0.01 higher than the rate currently in effect.

At the current assessment rate, assessment income would equal around $640,000, an amount insufficient to cover the Committee's anticipated expenditures, which include a $50,000 increase in funding for compliance. The Committee considered the proposed expenses and recommended increasing the assessment rate.

The major expenditures recommended by the Committee for the 2016–17 year include $600,248 for the Mexican fruit fly control program, $77,200 for management, and $50,000 for compliance. Budgeted expenses for these items in 2015–16 were $600,248, $77,200, and $0, respectively.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of Texas oranges and grapefruit. Orange and grapefruit shipments for the 2016–17 year are estimated at 8 million 7/10-bushel cartons or equivalent, which should provide $720,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, would be adequate to cover budgeted expenses. Funds in the reserve (currently around $367,000) would be kept within the maximum permitted by the order (approximately one fiscal period's expenses as stated in § 906.35).

The proposed assessment rate would continue in effect indefinitely unless modified, suspended, or terminated by USDA upon recommendation and information submitted by the Committee or other available information.

Although this assessment rate would be in effect for an indefinite period, the Committee would continue to meet prior to or during each fiscal period to recommend a budget of expenses and consider recommendations for modification of the assessment rate. The dates and times of Committee meetings are available from the Committee or USDA. Committee meetings are open to the public and interested persons may express their views at these meetings. USDA would evaluate Committee recommendations and other available information to determine whether modification of the assessment rate is needed. Further rulemaking would be undertaken as necessary. The Committee's 2016–17 budget and those for subsequent fiscal periods would be reviewed and, as appropriate, approved by USDA.

Initial Regulatory Flexibility Analysis

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601–612), the Agricultural Marketing Service (AMS) has considered the economic impact of this proposed rule on small entities. Accordingly, AMS has prepared this initial regulatory flexibility analysis.

The purpose of the RFA is to fit regulatory actions to the scale of businesses subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf.

There are approximately 170 producers of oranges and grapefruit in the production area and 13 handlers subject to regulation under the marketing order. Small agricultural producers are defined by the Small Business Administration (SBA) as those having annual receipts less than $750,000, and small agricultural service firms are defined as those whose annual receipts are less than $7,500,000 (13 CFR 121.201).

According to Committee data and information from the National Agricultural Statistics Service, the weighted average grower price for Texas citrus during the 2014–15 season was around $9.53 per box and total shipments were near 7.8 million boxes. Using the weighted average price and shipment information, and assuming a normal distribution of production, the majority of producers would have annual receipts of less than $750,000. In addition, based on Committee information, the majority of handlers have annual receipts of less than $7,500,000 and could be considered small businesses under SBA's definition. Thus, the majority of Texas citrus producers and handlers may be classified as small entities.

This proposal would increase the assessment rate established for the Committee and collected from handlers for the 2016–17 and subsequent fiscal periods from $0.08 to $0.09 per 7/10-bushel carton or equivalent of Texas oranges and grapefruit. The Committee unanimously recommended 2016–17 expenditures of $751,148 and an assessment rate of $0.09 per 7/10-bushel carton or equivalent handled. The proposed assessment rate of $0.09 is $0.01 higher than the 2015–16 rate. The quantity of assessable oranges and grapefruit for the 2016–17 season is estimated at 8 million 7/10-bushel cartons or equivalent. Thus, the $0.09 rate should provide $720,000 in assessment income. Income derived from handler assessments, along with interest income and funds from the Committee's authorized reserve, would be adequate to meet this year's expenses.

The major expenditures recommended by the Committee for the 2016–17 year include $600,248 for the Mexican fruit fly control program, $77,200 for management, and $50,000 for compliance. Budgeted expenses for these items in 2015–16 were $600,248, $77,200, and $0, respectively.

At the current assessment rate, assessment income would only equal around $640,000, an amount insufficient to cover the Committee's anticipated expenditures, which include a $50,000 increase in funding for compliance. The Committee considered the proposed expenses and recommended increasing the assessment rate.

Prior to arriving at this budget and assessment rate, the Committee considered information from various sources, such as the Committee's Budget and Personnel Committee, and Committee management. Alternative expenditure levels were discussed by these groups, based upon the relative value of various activities to the Texas citrus industry. Based on estimated shipments, the recommended assessment rate of $0.09 should provide $720,000 in assessment income. The Committee determined that the assessment revenue, along with funds from interest income and funds from reserves, would be adequate to cover budgeted expenses for the 2016–17 fiscal period.

A review of historical information and preliminary information pertaining to the upcoming crop year indicates that the average grower price for the 2016–17 season could be around $13.50 per 7/10-bushel carton or equivalent of oranges and grapefruit. Therefore, the estimated assessment revenue for the 2016–17 crop year as a percentage of total grower revenue would be around 0.6 percent.

This action would increase the assessment obligation imposed on handlers. While assessments impose some additional costs on handlers, the costs are minimal and uniform on all handlers. However, these costs would be offset by the benefits derived by the operation of the marketing order.

The Committee's meeting was widely publicized throughout the Texas citrus industry and all interested persons were invited to attend the meeting and participate in Committee deliberations on all issues. Like all Committee meetings, the June 2, 2016, meeting was a public meeting and all entities, both large and small, were able to express views on this issue. Finally, interested persons are invited to submit comments on this proposed rule, including the regulatory and informational impacts of this action on small businesses.

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), the order's information collection requirements have been previously approved by the Office of Management and Budget (OMB) and assigned OMB No. 0581–0189 Generic Fruit Crops. No changes in those requirements as a result of this action are necessary. Should any changes become necessary, they would be submitted to OMB for approval.

This proposed rule would impose no additional reporting or recordkeeping requirements on either small or large Texas orange and grapefruit handlers. As with all Federal marketing order programs, reports and forms are periodically reviewed to reduce information requirements and duplication by industry and public sector agencies.

AMS is committed to complying with the E-Government Act, to promote the use of the internet and other information technologies to provide increased opportunities for citizen access to Government information and services, and for other purposes.

USDA has not identified any relevant Federal rules that duplicate, overlap, or conflict with this action.

A small business guide on complying with fruit, vegetable, and specialty crop marketing agreements and orders may be viewed at: *http://www.ams.usda.gov/rules-regulations/moa/small-businesses.* Any questions about the compliance guide should be sent to Richard Lower at the previously-mentioned address in the **FOR FURTHER INFORMATION CONTACT** section.

A 30-day comment period is provided to allow interested persons to respond to this proposed rule. Thirty days is deemed appropriate because: (1) The 2016–17 fiscal period begins on August 1, 2016, and the marketing order requires that the rate of assessment for each fiscal period apply to all assessable Texas oranges and grapefruit handled during such fiscal period; (2) the Committee needs to have sufficient funds to pay its expenses which are incurred on a continuous basis; and (3) handlers are aware of this action which was unanimously recommended by the Committee at a public meeting and is similar to other assessment rate actions issued in past years.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 906 is proposed to be amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN LOWER RIO GRANDE VALLEY IN TEXAS

■ 1. The authority citation for 7 CFR part 906 continues to read as follows:

Authority: 7 U.S.C. 601–674.

■ 2. Section 906.235 is revised to read as follows:

§ 906.235 Assessment rate.

On and after August 1, 2016, an assessment rate of $0.09 per 7/10-bushel carton or equivalent is established for oranges and grapefruit grown in the Lower Rio Grande Valley in Texas.

Dated: August 12, 2016.

Elanor Starmer,

Administrator, Agricultural Marketing Service.

[FR Doc. 2016–19624 Filed 8–16–16; 8:45 am]

BILLING CODE 3410–02–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. FAA–2016–8844; Directorate Identifier 2016–NM–026–AD]

RIN 2120–AA64

Airworthiness Directives; The Boeing Company Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: We propose to adopt a new airworthiness directive (AD) for certain The Boeing Company Model 787–8 airplanes. This proposed AD was prompted by a report indicating that the fire block in the video control station and closets, and fire blocking tape in the floor panel opening in the forward and aft main passenger cabin, might be missing on some airplanes. This proposed AD would require installing fire block in the video control station and closets, as applicable, and installing fire blocking tape in the floor panel openings in the forward and aft main passenger cabin. We are proposing this AD to prevent propagation of a fire in the lower lobe cheek area outboard of a video control station and closet. Such propagation could result in an increased risk of smoke and/or fire propagation into the passenger cabin.

DATES: We must receive comments on this proposed AD by October 3, 2016.

ADDRESSES: You may send comments, using the procedures found in 14 CFR 11.43 and 11.45, by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Fax:* 202–493–2251.
- *Mail:* U.S. Department of Transportation, Docket Operations, M–30, West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., Washington, DC 20590.
- *Hand Delivery:* Deliver to Mail address above between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

For service information identified in this NPRM, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221. It is also available on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8844.

Examining the AD Docket

You may examine the AD docket on the Internet at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8844; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this proposed AD, the regulatory evaluation, any comments received, and other information. The street address for the Docket Office (phone: 800–647–5527) is in the **ADDRESSES** section. Comments will be available in the AD docket shortly after receipt.

FOR FURTHER INFORMATION CONTACT: Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle Aircraft Certification Office (ACO), 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6596; fax: 425–917–6590; email: *francis.smith@faa.gov.*

SUPPLEMENTARY INFORMATION:

Comments Invited

We invite you to send any written relevant data, views, or arguments about this proposal. Send your comments to an address listed under the **ADDRESSES** section. Include "Docket No. FAA–2016–8844; Directorate Identifier 2016–NM–026–AD" at the beginning of your comments. We specifically invite comments on the overall regulatory, economic, environmental, and energy aspects of this proposed AD. We will consider all comments received by the closing date and may amend this proposed AD because of those comments.

We will post all comments we receive, without change, to *http://www.regulations.gov,* including any personal information you provide. We will also post a report summarizing each substantive verbal contact we receive about this proposed AD.

Discussion

We have received a report from Boeing indicating that the fire block in the video control station and closets, and fire blocking tape in the floor panel opening in the forward and aft main passenger cabin might be missing on some airplanes. The materials were not installed during production. We are proposing this AD to prevent propagation of a fire in the lower lobe cheek area outboard of a video control station and closet. Such propagation could result in an increased risk of smoke and/or fire in the passenger cabin.

Related Service Information Under 1 CFR Part 51

We reviewed the following service information:

Boeing Alert Service Bulletin B787–81205–SB250028–00, Issue 001, dated August 1, 2013. The service information describes procedures for installing fire block in the video control station and closets.

Boeing Alert Service Bulletin B787–81205–SB250070–00, Issue 001, dated March 10, 2015. The service information describes procedures for installing fire block in the video control station.

Boeing Alert Service Bulletin B787–81205–SB530018–00, Issue 001, dated June 7, 2013. The service information describes procedures for installing fire blocking tape in the floor panel openings in the forward and aft main passenger cabin.

This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the **ADDRESSES** section.

FAA's Determination

We are proposing this AD because we evaluated all the relevant information and determined the unsafe condition described previously is likely to exist or develop in other products of the same type design.

Proposed AD Requirements

This proposed AD would require accomplishing the actions specified in the service information described previously. For information on the procedures and compliance times, see this service information at *http://www.regulations.gov* by searching for and locating Docket No. FAA–2016–8844.

Costs of Compliance

We estimate that this proposed AD affects 6 airplanes of U.S. registry. We estimate the following costs to comply with this proposed AD:

ESTIMATED COSTS

Action	Labor cost	Parts cost	Cost per product	Cost on U.S. operators
Fire blocking tape installation in the floor panel openings.	Up to 23 work-hours × $85 per hour = $1,955 per installation.	$0	Up to $1,955 per installation.	Up to $11,730 per installation.
Fire block installation in the video control closet.	5 work-hours × $85 per hour = $425 per installation.	489	$914 per installation	$5,484 per installation.
Fire block installation in the video control station.	5 work-hours × $85 per hour = $425 per installation.	276	$701 per installation	$4,206 per installation.

According to the manufacturer, some of the costs of this proposed AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all costs in our cost estimate.

Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA's authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. Subtitle VII: Aviation Programs, describes in more detail the scope of the Agency's authority.

We are issuing this rulemaking under the authority described in Subtitle VII, Part A, Subpart III, Section 44701: "General requirements." Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

Regulatory Findings

We determined that this proposed AD would not have federalism implications under Executive Order 13132. This proposed AD would not have a substantial direct effect on the States, on the relationship between the national Government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify this proposed regulation:

(1) Is not a "significant regulatory action" under Executive Order 12866,

(2) Is not a "significant rule" under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979),

(3) Will not affect intrastate aviation in Alaska, and

(4) Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

The Proposed Amendment

■ Accordingly, under the authority delegated to me by the Administrator, the FAA proposes to amend 14 CFR part 39 as follows:

PART 39—AIRWORTHINESS DIRECTIVES

■ 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

■ 2. The FAA amends § 39.13 by adding the following new airworthiness directive (AD):

The Boeing Company: Docket No. FAA–2016–8844; Directorate Identifier 2016–NM–026–AD.

(a) Comments Due Date

We must receive comments by October 3, 2016.

(b) Affected ADs

None.

(c) Applicability

This AD applies to The Boeing Company Model 787–8 airplanes, certificated in any category, as identified in Boeing Alert Service Bulletin B787–81205–SB530018–00, Issue 001, dated June 7, 2013; Boeing Alert Service Bulletin B787–81205–SB250028–00, Issue 001, dated August 1, 2013; and Boeing Alert Service Bulletin B787–81205–SB250070–00, Issue 001, dated March 10, 2015.

(d) Subject

Air Transport Association (ATA) of America Code 25, Equipment/furnishings; 53, Fuselage.

(e) Unsafe Condition

This AD was prompted by a report indicating that the fire block in the video control station and closets, and fire blocking tape in the floor panel opening in the forward and aft main passenger cabin, might be missing on some airplanes. We are issuing this AD to prevent propagation of a fire in the lower lobe cheek area outboard of a video control station and closet. Such propagation could result in an increased risk of smoke and/or fire propagation into the passenger cabin.

(f) Compliance

Comply with this AD within the compliance times specified, unless already done.

(g) Installation of Fire Block and Fire Blocking Tape, as Applicable

Within 72 months after the effective date of this AD, do the actions specified in paragraphs (g)(1), (g)(2), and (g)(3) of this AD, as applicable.

(1) For airplanes specified in Boeing Alert Service Bulletin B787–81205–SB250028–00, Issue 001, dated August 1, 2013: Install fire block in the video control station and closets, as applicable, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB250028–00, Issue 001, dated August 1, 2013.

(2) For airplanes specified in Boeing Alert Service Bulletin B787–81205–SB250070–00, Issue 001, dated March 10, 2015: Install fire block in the video control station, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB250070–00, Issue 001, dated March 10, 2015.

(3) For airplanes specified in Boeing Alert Service Bulletin B787–81205–SB530018–00, Issue 001, dated June 7, 2013: Install fire blocking tape in the floor panel opening in the forward and aft main passenger cabin, in accordance with the Accomplishment Instructions of Boeing Alert Service Bulletin B787–81205–SB530018–00, Issue 001, dated June 7, 2013.

(h) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle Aircraft Certification Office (ACO), FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (i)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane, and the approval must specifically refer to this AD.

(4) For service information that contains steps that are labeled as Required for Compliance (RC), the provisions of paragraphs (h)(4)(i) and (h)(4)(ii) of this AD apply.

(i) The steps labeled as RC, including substeps under an RC step and any figures identified in an RC step, must be done to comply with the AD. An AMOC is required for any deviations to RC steps, including substeps and identified figures.

(ii) Steps not labeled as RC may be deviated from using accepted methods in accordance with the operator's maintenance or inspection program without obtaining approval of an AMOC, provided the RC steps, including substeps and identified figures, can still be done as specified, and the airplane can be put back in an airworthy condition.

(i) Related Information

(1) For more information about this AD, contact Francis Smith, Aerospace Engineer, Cabin Safety and Environmental Systems Branch, ANM–150S, FAA, Seattle ACO, 1601 Lind Avenue SW., Renton, WA 98057–3356; phone: 425–917–6596; fax: 425–917–6590; email: *francis.smith@faa.gov.*

(2) For service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone: 206–544–5000, extension 1; fax: 206–766–5680; Internet: *https://www.myboeingfleet.com.* You may view this referenced service information at the FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

Issued in Renton, Washington, on August 5, 2016.

Chris L. Spangenberg,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–19487 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 71

[Docket No. FAA–2016–7417; Airspace Docket No. 16–AWA–4]

RIN 2120–AA66

Proposed Amendment of Class C Airspace; El Paso International Airport, TX

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This action proposes to modify Class C airspace at El Paso International Airport, El Paso, TX, by removing a cutout from the Class C airspace area that excludes the airspace within a 2-mile radius of West Texas Airport and the airspace beyond an 8-mile arc from the El Paso International Airport beginning at the 115° bearing from the airport clockwise to the Rio Grande River. Additionally, this proposal would update the El Paso International Airport geographic coordinates to reflect the current airport reference point (ARP) information in the FAA's aeronautical database and remove the West Texas Airport and geographic coordinate references from the Class C airspace description. The FAA is proposing this action to enable more efficient operations at El Paso International Airport.

DATES: Comments must be received on or before October 17, 2016.

ADDRESSES: Send comments on this proposal to the U.S. Department of Transportation, Docket Operations, 1200 New Jersey Avenue SE., West Building

Ground Floor, Room W12–140, Washington, DC 20590–0001; telephone: 1 (800) 647–5527, or (202) 366–9826. You must identify FAA Docket No. FAA–2016–7417 and Airspace Docket No. 16–AWA–4 at the beginning of your comments. You may also submit comments through the Internet at *http://www.regulations.gov.*

You may review the public docket containing the proposal, any comments received, and any final disposition in person in the Dockets Office between 9:00a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. The Docket Office (telephone 1(800) 647–5527), is on the ground floor of the building at the above address.

FAA Order 7400.9Z, Airspace Designations and Reporting Points, and subsequent amendments can be viewed online at *http://www.faa.gov/air_traffic/publications/*. For further information, you can contact the Airspace Policy Group, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783. The Order is also available for inspection at the National Archives and Records Administration (NARA). For information on the availability of FAA Order 7400.9Z at NARA, call (202) 741–6030, or go to *http://www.archives.gov/federal_register/code_of_federal-regulations/*ibr_locations.html. FAA Order 7400.9, Airspace Designations and Reporting Points, is published yearly and effective on September 15.

FOR FURTHER INFORMATION CONTACT: Colby Abbott, Airspace Policy Group, Office of Airspace Services, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 267–8783.

SUPPLEMENTARY INFORMATION:

Authority for This Rulemaking

The FAA's authority to issue rules regarding aviation safety is found in Title 49 of the United States Code. Subtitle I, Section 106 describes the authority of the FAA Administrator. Subtitle VII, Aviation Programs, describes in more detail the scope of the agency's authority. This rulemaking is promulgated under the authority described in Subtitle VII, Part A, Subpart I, Section 40103. Under that section, the FAA is charged with prescribing regulations to assign the use of the airspace necessary to ensure the safety of aircraft and the efficient use of airspace. This regulation is within the scope of that authority as it would modify terminal airspace as required to preserve the safe and efficient flow of air traffic in the El Paso, TX, area.

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify both docket numbers (FAA Docket No. FAA–2016–7417 and Airspace Docket No. 16–AWA–4) and be submitted in triplicate to the Docket Management Facility (see **ADDRESSES** section for address and phone number). You may also submit comments through the internet at *http://www.regulations.gov.*

Commenters wishing the FAA to acknowledge receipt of their comments on this action must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to FAA Docket No. FAA–2016–7417 and Airspace Docket No. 16–AWA–4." The postcard will be date/time stamped and returned to the commenter.

All communications received on or before the specified comment closing date will be considered before taking action on the proposed rule. The proposal contained in this action may be changed in light of comments received. All comments submitted will be available for examination in the public docket both before and after the comment closing date. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRMs

An electronic copy of this document may be downloaded through the internet at *http://www.regulations.gov.*

You may review the public docket containing the proposal, any comments received and any final disposition in person in the Dockets Office (see **ADDRESSES** section for address and phone number) between 9:00 a.m. and 5:00 p.m., Monday through Friday, except Federal holidays. An informal docket may also be examined during normal business hours at the office of the Operations Support Group, Central Service Center, Federal Aviation Administration, 10101 Hillwood Blvd., Fort Worth, TX, 76177.

Availability and Summary of Documents for Incorporation by Reference

This document proposes to amend FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015. FAA Order 7400.9Z is publicly available as listed in the **ADDRESSES** section of this document. FAA Order 7400.9Z lists Class A, B, C, D, and E airspace areas, air traffic service routes, and reporting points.

The Proposal

The FAA is proposing an amendment to Title 14, Code of Federal Regulations (14 CFR) part 71 to modify the El Paso International Airport, TX, Class C airspace area. The proposal would remove a cutout and reduced perimeter boundary arc that excludes the airspace within a 2-mile radius of the West Texas Airport and the airspace beyond an 8-mile arc from the El Paso International Airport beginning at the 115° bearing from the airport clockwise to the Rio Grande River. These exclusions from the Class C airspace area were established to accommodate operations at West Texas Airport, which was located approximately 9 nautical miles (NM) southeast of El Paso International Airport. The West Texas Airport (renamed Horizon Airport in 2004) is now permanently closed and the property sold for non-aviation uses. Since the original purpose for the exclusions no longer exists, the FAA is proposing to remove the words ". . . that airspace beyond an 8-mile arc from the El Paso International Airport beginning at the 115° bearing from the airport clockwise to the Rio Grande River, and that airspace within a 2-mile radius of the West Texas Airport, and . . ." from the regulatory text. The West Texas Airport and geographic coordinate references would also be removed from the Class C airspace description. These changes would restore the Class C airspace that extends upward from 5,200 feet MSL to 8,000 feet MSL to a standard configuration 10–NM radius boundary southeast of the El Paso International Airport and enhance the management of aircraft operations to and from the airport.

Additionally, the FAA would change the exclusion language pertaining to the Class C airspace extending upward from 5,200 feet MSL from ". . . that airspace within Mexico, and that airspace west of long 106°27′02″ W." to ". . . that airspace west of long. 106°27′02″ W., and that airspace within Mexico." This change would be editorial for format and clarity to standardize the exclusion information associated with the Class C airspace surface area and shelf.

Lastly, this action would update the El Paso International Airport geographic coordinates to reflect the current ARP information in the FAA's aeronautical database from "lat. 31°48′24″ N., long. 106°22′40″ W." to "lat. 31°48′26″ N., long. 106°22′35″ W."

Class C airspace areas are published in paragraph 4000 of FAA Order 7400.9Z, dated August 6, 2015 and effective September 15, 2015, which is incorporated by reference in 14 CFR 71.1. The Class C airspace area modification proposed in this document would be published subsequently in the Order.

Regulatory Notices and Analyses

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (1) Is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under Department of Transportation (DOT) Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this proposed rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This proposal will be subject to an environmental analysis in accordance with FAA Order 1050.1F, "Environmental Impacts: Policies and Procedures" prior to any FAA final regulatory action.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—DESIGNATION OF CLASS A, B, C, D, AND E AIRSPACE AREAS; AIR TRAFFIC SERVICE ROUTES; AND REPORTING POINTS

■ 1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. 106(f), 106(g); 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959–1963 Comp., p. 389.

§ 71.1 [Amended]

■ 2. The incorporation by reference in 14 CFR 71.1 of the FAA Order 7400.9Z, Airspace Designations and Reporting Points, dated August 6, 2015, and effective September 15, 2015, is amended as follows:

Paragraph 4000—Subpart C—Class C Airspace

* * * * *

ASW TX C El Paso International Airport, TX [Amended]

El Paso International Airport, TX
(Lat. 31°48′26″ N., long. 106°22′35″ W.)

That airspace extending upward from the surface to and including 8,000 feet MSL within a 5-mile radius of the El Paso International Airport, excluding that airspace west of long. 106°27′02″ W., and that airspace within Mexico; and that airspace extending upward from 5,200 feet MSL to and including 8,000 feet MSL within a 10-mile radius of the El Paso International Airport, excluding that airspace west of long. 106°27′02″ W., and that airspace within Mexico.

Issued in Washington, DC, on August 10, 2016.

M. Randy Willis,

Acting Manager, Airspace Policy Group.

[FR Doc. 2016–19556 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–13–P

CONSUMER PRODUCT SAFETY COMMISSION

16 CFR Part 1308

[Docket No. CPSC–2016–0017]

Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics

AGENCY: U.S. Consumer Product Safety Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Consumer Product Safety Commission (Commission, or CPSC) is proposing a rule to determine that certain plastics with specified additives would not contain the specified phthalates prohibited in children's toys and child care articles. Based on these determinations, the specified plastics with specified additives would not require third party testing for compliance with the mandatory phthalates prohibitions on children's toys and child care articles.

DATES: Submit comments by October 31, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CPSC–2016–0017, by any of the following methods:

Electronic Submissions: Submit electronic comments to the Federal eRulemaking Portal at: *http://www.regulations.gov.* Follow the instructions for submitting comments. The Commission does not accept comments submitted by electronic mail (email), except through *regulations.gov.* The Commission encourages you to submit electronic comments by using the Federal eRulemaking Portal, as described above.

Written Submissions: Submit written comments by mail/hand delivery/courier to: Office of the Secretary, Consumer Product Safety Commission, Room 820, 4330 East West Highway, Bethesda, MD 20814; telephone (301) 504–7923.

Instructions: All submissions received must include the agency name and docket number. All comments received may be posted without change, including any personal identifiers, contact information, or other personal information provided, to: *http://www.regulations.gov.* Do not submit confidential business information, trade secret information, or other sensitive or protected information that you do not want to be available to the public. If furnished at all, such information should be submitted in writing by mail/hand delivery/courier.

FOR FURTHER INFORMATION CONTACT: Randy Butturini, Project Manager, Office of Hazard Identification and Reduction U.S. Consumer Product Safety Commission, 4330 East West Hwy., Room 814, Bethesda, MD 20814; 301–504–7562: email; *rbutturini@cpsc.gov.*

SUPPLEMENTARY INFORMATION:

A. Background

1. Third Party Testing and Burden Reduction

Section 14(a) of the Consumer Product Safety Act, (CPSA), as amended by the Consumer Product Safety Improvement Act of 2008 (CPSIA), requires that manufacturers of products subject to a consumer product safety rule or similar rule, ban, standard, or regulation enforced by the CPSC, must certify that the product complies with all applicable CPSC-enforced requirements. 15 U.S.C. 2063(a). For children's products, certification must be based on testing conducted by a CPSC-accepted third party conformity assessment body. *Id.* Public Law 112–28 (August 12, 2011) directed the CPSC to seek comment on "opportunities to reduce the cost of third party testing requirements consistent with assuring compliance with any applicable consumer product safety rule, ban, standard, or regulation.'' Public Law 112–28 also authorized the Commission to issue new or revised third party testing regulations if the Commission determines ''that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations.'' *Id.* 2063(d)(3)(B).

2. Prohibitions in Section 108 of the CPSIA

Section 108 of the CPSIA prohibits children's toys and child care articles that contain six specified phthalates in concentrations above 0.1 percent in ''accessible plasticized component parts and other component parts made of materials that may contain phthalates.'' The prohibited phthalates in section 108 of the CPSIA are listed in Table 1. Children's toys and child care articles subject to the content limits in section 108 of the CPSIA require third party testing for compliance with the phthalate content limits before the manufacturer can issue a Children's Product Certificate (CPC) and enter the children's toys or child care articles into commerce.

TABLE 1—STATUTORILY PROHIBITED PHTHALATES

Permanent prohibition on phthalates in children's toys and child care articles
DEHP: di-(2-ethylhexyl) phthalate DBP: dibutyl phthalate BBP: benzyl butyl phthalate
Interim prohibition on phthalates in children's toys and child care articles
DINP: diisononyl phthalate DIDP: diisodecyl phthalate DnOP: di-n-octyl phthalate

The CPSIA required the Commission to appoint a Chronic Hazard Advisory Panel (CHAP) to ''study the effects on children's health of all phthalates and phthalate alternatives as used in children's toys and child care articles.'' The CHAP issued its report in July 2014.[1] Based on the CHAP report, the Commission published a notice of proposed rulemaking (NPR) [2] proposing to make the interim prohibition on DINP in children's toys and child care articles permanent, and proposing to lift the interim statutory prohibitions on DIDP and DnOP in children's toys and child care articles. In addition, the NPR proposed adding four new phthalates to the prohibited list of phthalates that cannot exceed 0.1 percent concentration in accessible component parts of children's' toys and child care articles, Table 2 contains the list of phthalates that the NPR proposed to prohibit in children's toys and child care articles.

TABLE 2—PROPOSED PROHIBITED PHTHALATES

Phthalates
DEHP: di-(2-ethylhexyl) phthalate DBP: dibutyl phthalate BBP: benzyl butyl phthalate DINP: diisononyl phthalate DIBP: diisobutyl phthalate DPENP: di-n-pentyl phthalate DHEXP: di-n-hexyl phthalate DCHP: dicyclohexyl phthalate

B. Contractor's Research on Phthalates in Consumer Products

CPSC contracted with Toxicology Excellence for Risk Assessment (TERA) to conduct research on phthalates and provide CPSC with two research reports on phthalates relevant to this rulemaking. TERA conducted a literature search on the production and use of 11 specified phthalates in consumer products (Task 11 Report).[3] The 11 phthalates researched by TERA are based on the phthalates assessed by the CHAP and the recommendations made in the CHAP report. Additionally, the CPSC contracted with TERA to conduct a literature search on whether specified plastics could be determined not to contain any of the 11 phthalates in concentrations above the CPSIA limit of 0.1 percent (Task 12 Report).[4]

TERA used a tiered literature research approach to identify sources for review from among the ''universe'' of available data. The tiers were used to provide a structured search method to locate relevant sources and eliminate unrelated material. TERA used books, factsheets, journal articles, patents, and other sources as primary and secondary literature sources. The use of this tiered approach resulted in a comprehensive review of the available literature that is representative of the information available on the potential for the presence of any of the 11 phthalates in the 4 specified plastics.

TERA screened over 119,800 studies identified by the above described tiered search method for relevance to the 11 phthalates and 4 plastics. CPSC staff reviewed the information provided in the contractor report and formulated recommendations for Commission consideration based on TERA's research.

The plastics researched by TERA were:

- Polypropylene (PP);
- Polyethylene (PE);
- High-impact polystyrene (HIPS); and
- Acrylonitrile butadiene styrene (ABS).

TERA's research included the following factors:

- The raw materials used in the production of the specified plastics;
- The manufacturing processes used worldwide to produce the plastics;
- Typical applications for the specified plastics in consumer products, especially toys and child care articles, focusing on circumstances where the plastic could contain phthalates at concentrations greater than 0.1 percent;
- The potential use of recycled materials containing the specified phthalates in the production of the plastics; and
- The potential for phthalate contamination during packaging, storage, use, or other factors.

C. CPSC Staff Analysis

1. Polypropylene (PP)

TERA's research indicated the production of PP plastic uses a PP monomer, ethylene, and other monomers, a hydrocarbon solvent, catalysts, nucleating agents or fillers, and a number of other additives, depending on the type of PP and other manufacturing considerations. Additives can be included in PP to achieve various chemical and mechanical characteristics. PP can include the following additives:

- *Hydrocarbon solvents:* Examples of solvents used are hexane and heptane;

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[1] *http://www.cpsc.gov/PageFiles/169902/CHAP-REPORT-With-Appendices.pdf.*

[2] *https://www.federalregister.gov/articles/2014/12/30/2014-29967/prohibition-of-childrens-toys-and-child-care-articles-containing-specified-phthalates.*

[3] *http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/TERAReportPhthalates.pdf.* The work was conducted as a task order (Task 11) under CPSC contract CPSC–D–12–0001.

[4] *http://www.cpsc.gov//Global/Research-and-Statistics/Technical-Reports/Other%20Technical%20Reports/ReportonPhthalatesinFourPlastics.pdf.* The work was conducted as a task order (Task 12) under CPSC contract CPSC–D–12–0001.

- *Catalysts:*[5] Catalysts used in producing PP are the Ziegler-Natta catalysts;[6]
- *Fillers:* Fillers are added to plastics to enhance their performance (*e.g.,* impact resistance, shrink resistance), and reduce manufacturing costs. Examples of fillers used in PP include talc, calcium carbonate, and fiberglass;
- *Primary antioxidants:* Antioxidants inhibit oxidative deterioration of a material. Primary antioxidants donate hydrogen atoms to prevent free radical creation. Examples of primary antioxidants include hindered phenol, such as butylated hydroxytoluene, and hindered amine light stabilizers;
- *Secondary antioxidants:* Secondary antioxidants prevent degradation by breaking down free radicals and hydroperoxides, and synergize with the primary antioxidants. Examples of secondary antioxidants include phosphites and thioesters;
- *Neutralizing agents:* Neutralizing agents adjust the acidity of the chemicals during production, and can include calcium and zinc stearate, zeolites, calcium and zinc oxides, and metallic salts of lactic or benzoic acid;
- *Antistatic agents:* Antistatic agents reduce the buildup of static electricity, and can include cationic compounds, anionic compounds, and nonionic compounds;
- *Slip agents:* Slip agents are added to reduce a plastic surface's coefficient of friction. Examples of slip agents include modified fatty acids or fatty amides;
- *Metal deactivators:* Transition metals like copper and iron can accelerate plastic degradation. Metal deactivators, such as N,N′-dibenzaloxaldihydrazide, combine with the metal ions and prevent catalytic degradation of the plastic;
- *Quenchers:* Quenchers scavenge stray free radicals and decompose unwanted peroxides. Examples of quenchers are organic nickel complexes, nickel salts of thiocarbamate, and nickel complexes with alkylated phenol phosphonates;
- *UV stabilizers:* Ultraviolet (UV) stabilizers are added to PP to protect the plastic from degradation in sunlight. Examples of UV stabilizers are hindered amine light stabilizers, carbon black, titanium dioxide, zinc oxide, derivatives of benzophenone, benzotriazoles, phenyl, aryl, or acrylic esters, formamidines, and oxanilides;
- *Nucleating agents:* Nucleating agents are additives that increase the crystallization of a plastic from a liquid solution. Examples of nucleating agents for PP include carboxylic acids, benzyl sorbitols, and salts of organic phosphates;
- *Flame retardants:* Examples of flame retardants include brominated flame retardants, cycloaliphatic chlorines; antimony trioxide, ferric oxide, zinc oxide, zinc borate, barium metaborates; phosphorus flame retardants, magnesium hydroxide, and aluminum hydroxide;
- *Blowing or foaming agents:* Blowing and foaming agents create gas bubbles during molding, resulting in a foamed plastic. Examples of blowing and foaming agents include sodium bicarbonate, sodium borohydride, polycarbonic acid, citric acid, 4,4′oxybis(benzenesulfonyl hydrazide), azodicarbonamide, or para-toluenesulfonyl semicarbazide;
- *Antiblocking agents:* Antiblocking agents are used to prevent plastic films from sticking together through cold flow or static electricity. Examples of antiblocking agents include natural and manufactured waxes, metallic salts of fatty acids, silica compounds, and some polymers (*e.g.,* polyvinyl alcohol, polyamides, polyethylene, polysiloxanes, and fluoroplastics);
- *Lubricants:* Lubricants are used in PP (and other plastics) to lower the molten material's coefficient of viscosity and prevent the plastic from sticking to metal surfaces. The lubricants allow the plastic's hydrocarbon chains to slip past each other in the melt. Examples of lubricants include metal soaps, hydrocarbon waxes, polyethenes, amide waxes, fatty acids, and fatty alcohols, (*e.g.,* calcium or zinc stearates); or
- *Colorants:* Colorants for plastics typically consist of dyes, in which the color-producing material is dissolved in a carrier medium, and pigments, in which very small particles of the color-producing material are suspended in the carrier medium. Examples of colorants used in PP include heavy metal-based oxides, sulfides, chromates, and other complexes, including cadmium, zinc, titanium, lead, molybdenum; and ultramines (sulfide-silicate complexes containing sodium and aluminum; azo pigments).

The research showed that among all of these raw materials and additives, only Ziegler-Natta catalysts may contain one or more of the prohibited phthalates. Ziegler-Natta catalysts are generally titanium-based catalyst systems in combination with an organoaluminum co-catalyst, and an internal donor (a molecule that contributes an electron to the chemical reaction), such as DBP, DIBP or DEHP. As described in the Task 12 Report, these catalysts may survive the plastic's polymerization process, and the phthalates may be present in the final plastic pellets, theoretically at concentrations of about 1 mg/kg (1 part per million, "ppm"). The Task 12 Report references an industry analysis in the context of European regulations that indicates that phthalate concentrations in PP do not exceed 0.15 mg/kg (0.15 ppm) and are often below the measurement threshold of the analytical method of 0.01 mg/kg (0.01 ppm).

2. Polyethylene (PE)

TERA's research indicated that PE is manufactured using PE monomers or certain copolymers or other monomers, and a number of additives. Additives can be included in PE to achieve various chemical and mechanical characteristics. PE can include the following additives:

- *Plasticizers:*[7] Examples of plasticizers for PE include glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, EVA polymer, DOP;[8]
- *Initiators:* Initiators help form the plastic macromolecules from the solution. Examples of PE initiators are benzoyl peroxide, azodiisobutyronitrile, and oxygen;
- *Promoters:* Promoters in PE improve paint adhesion and resistance to some solvents. PE promoters include sodium and calcium (in metal or hydride form);
- *Catalysts:* Catalysts for PE include the Ziegler-Natta catalysts, and metallocene catalysts (*e.g.,* zirconium, titanium);
- *Fillers:* silane and titanate coupling agents are used as fillers in PE;
- *Antistatic agents:* PE antistatic agents include polyethylene glycol alkyl esters;

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[5] The Merriam-Webster online dictionary defines a "catalyst" as "a substance that causes or accelerates a chemical reaction without itself being affected." A catalyst is not consumed, altered, or incorporated into one of the reaction's products.

[6] A Ziegler–Natta catalyst, named after Karl Ziegler and Giulio Natta, is a class of catalyst used in the production of some plastics.

[7] The Task 12 Report indicated that several prohibited phthalates are used as plasticizers in PE. CPSC staff reviewed the report's references for this information. As cited in the Task 12 Report, Bhunia et al. (2013) reported several phthalates used in food packaging plastic films, including PE, referencing Sablani and Rahman (2007). In the latter reference, staff did not find any support for the claimed uses of phthalates. In fact, in the section on plasticizers, Sablani and Rahman (2007) stated that most plasticizers are used in PVC and that as a result of studies on migration of plasticizers from food packaging, ". . . industry has replaced PVC with other polymers, such as PE or regenerated cellulose not associated with plasticizers." (emphasis added)

[8] The isomer of DOP was not specified. DOP can include DEHP.

- *Flame retardants:* PE flame retardants include antimony trioxide, and halogenated substances;
- *Anti-blocking agents:* Fine silicas are an example of a PE antiblocking agent;
- *Slip agents:* PE slip agents include fatty acid amides such as oleamide and erucamide;
- *Blowing agents:* PE blowing agents include 4,4′-oxybisbenzenesulfonohydrazine and azocarbonamide;
- *Cross-linking agents:* Cross-linking agents set up chemical bonds between the plastic macromolecules and assists in "curing" the plastic. Examples of cross-linking agents include dicumyl peroxide, and vinyl silanes;
- *Antioxidants:* PE antioxidants include 4-methyl-2,6-t-butyl phenol, 1,1,3-tris-(4-hydroxy-2-methyl-5-butylphenyl)butane, bis-[2-hydroxy-5-methyl-3-(1-methylcyclohexyl)phenyl]-methane, and dilauryl-β,β′-thiodipropionate;
- *Carbon black;* or
- *Colorants:* PE colorants are often based on cobalt, cadmium, and manganese.

As with PP, PE catalysts include an internal donor, such as DBP, DIBP, or DEHP, although the phthalate concentration in the final plastic is generally well below 0.15 mg/kg (0.15 ppm).

One reference in the Task 12 report indicated that DOP can be used as a plasticizer in PE. Staff reviewed the cited references, as well as citations within the references, and found that uses of DOP in PE are mentioned in patents for specialized materials with no known current consumer product application, or may be used in materials, such as pavement marking, which are not children's products. One cited patent described use of phthalates in a PE microporous film used as an internal separator for lithium ion batteries.

The Task 12 Report cited a patent for a material made with PE plastic and DBP for use as a surface for outdoor athletic track, basketball, volleyball, and playgrounds. CPSC staff found no information indicating that such a product has been manufactured and marketed for consumer use. Furthermore, the applications for the material do not include children's toys or child care articles that are subject to the phthalate content restrictions.

3. High-Impact Polystyrene (HIPS)

TERA's research indicated that HIPS is a plastic blend generally produced from styrene, polybutadiene rubber, benzene, and a number of other substances. Additives can be included in HIPS to achieve various chemical and mechanical characteristics. HIPS can include the following additives:

- *Catalysts:* The Ziegler-Natta catalysts;
- *Internal lubricant:* Zinc stearate is a lubricant for HIPS;
- *Chain transfer/transition agent:* Chain transfer/transition agents regulate the length of the HIPS macromolecules. HIPS chain transfer/transition agents include tertdocecylmercaptan and liquid paraffin;
- *Stabilizer:* Tert-butylcatechol is a stabilizer for HIPS;
- *Diluents:* Diluents are used to reduce the concentration of a plastic as a means to reduce the plastic's viscosity and to modify its processing conditions. Examples of HIPS diluents include ethylbenzene, and toluene; or
- *Colorants:* HIPS colorants include azo dyes, anthraquinone dyes, perinone dyes, or xanthene dyes.
- *Other additives:* Additional materials used in the manufacture of HIPS include:
  - ○ Aluminum chloride, ethyl chloride, hydrochloric acid;
  - ○ Iron oxide, potassium oxide, chromium oxide; and
  - ○ Bifunctional peroxides.

As with PP and PE, the polybutadiene used in HIPS production is made with the use of catalysts that include an internal donor, such as DBP, DIBP, or DEHP. Although no testing for phthalate content was located, because the use of phthalate in HIPS is as a catalyst, the concentration in the final product is expected to be well below 0.1 percent.

4. Acrylonitrile Butadiene Styrene (ABS)

TERA's research indicated that ABS plastic is manufactured with specific monomers, such as acrylonitrile, butadiene, and styrene, trans-1,4-butadiene, cis-1,4-butadiene, and 1,2-butadiene. Additives are included in ABS to achieve various chemical and mechanical characteristics. ABS can include the following additives:

- *Plasticizers:* ABS plasticizers include hydrocarbon processing oil, triphenyl phosphate, resorcinol bis(diphenyl phosphate), oligomeric phosphate, long chain fatty acid esters, and aromatic sulfonamide;
- *Hydrocarbon solvents:* hexane, heptane, and ethyl benzene;
- *Stabilizers against heat or light degradation:* Stabilizer examples include phenolic antioxidants, thiol-containing antioxidants, phosphites, thioesters, substituted benzophenones and benzotriazoles, and hindered amines;
- *Lubricants:* ABS lubricants include metallic stearates, montan waxes or amide waxes;[9]
- *Antioxidants:* Phenolic-based or phosphate-based antioxidants are used in the manufacture of ABS;
- *Molecular weight regulator:* An example of an ABS molecular-weight regulator is *tert*-dodecyl mercaptan;
- *Initiators/catalysts:* ABS initiators and catalysts include potassium persulfate, sodium persulfate, oil-soluble initiators in a redox system (cumene hydroperoxide, sodium pyrophosphate, dextrose, and iron (II) sulfate);
- *Activators:* Activators prepare the ABS surface for electroplating. The activators in ABS are often palladium and tin salts in an acid solution;[10]
- *Emulsifiers:* Emulsifiers are chemicals that promote the mixing of hydrophilic and hydrophobic materials. ABS emulsifiers include salts of rosin, fatty sodium lauryl sulfate, and oleate;
- *Colorants:* ABS colorants include phthalocyanines, perylenes, cromophtals, titanium dioxide, carbon black, black iron oxide, ultramarine blue, red iron oxide, and aluminum flake.[11]

5. Additional CPSC Staff Research

TERA's research did not include an examination of the colorants in polyethylene, high-impact polystyrene, or acrylonitrile butadiene styrene. TERA's research also did not include an examination of the lubricants, activators, and antioxidants that could be used in the production of ABS. CPSC staff conducted additional research into these component parts of the plastics.

6. Potential Phthalate Use in the Four Plastics

The Task 11 Report indicates that phthalates are used generally as plasticizers or softeners of certain plastics, primarily polyvinyl chloride (PVC), as solvents, and as components of inks, paints, adhesives, and sealants. Except for the general category of inks and colorants, the Task 11 Report did not indicate uses of the prohibited phthalates in any of the four plastics, in the raw materials, or in the types of additives that might be used in the four plastics.

The four plastics may also be used as ingredients in a variety of materials. For example, PP may be used in formulations for concrete, paints, and lubricating grease. These materials would not be considered to be PP plastic. PE, HIPS, ABS also may be used as additives in materials that would not be considered plastics.

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[9] The TERA Task 12 Report did not specify ABS lubricants. CPSC staff supplemented the Task 12 Report with additional research.

[10] The TERA Task 12 Report did not specify ABS activators. CPSC staff supplemented the Task 12 Report with additional research.

[11] The TERA Task 12 Report did not specify ABS colorants. CPSC staff supplemented the Task 12 Report with additional research.

The TERA Task 11 and Task 12 Reports indicate that the phthalates researched are not associated with the chemistry and applications of the plastics PP, PE, HIPS, or ABS. When these plastics are plasticized, materials other than the phthalates are used as plasticizers (*e.g.*, hydrocarbon processing oil, phosphate esters, long chain fatty acid esters, and aromatic sulfonamide for ABS). TERA found one reference in which DnOP (also referred to as DOP) was used as a plasticizer for PE. However, the only application cited was a patent for a microporous plastic film used in the production of lithium-ion batteries. TERA's research included references prior to and after the enactment of the CPSIA, none of which indicated any phthalate use in the four plastics.

7. Studies Where Phthalates Were Detected

TERA's investigation of the uses of the four plastics shows that all four are used to make plastic consumer products and component parts. None of these applications specifically includes phthalates, although a few studies of the phthalate content of products were located.

Several studies evaluated food, beverage, and cosmetics packaging made with PP, PE, and polystyrene (PS). These studies generally measured migration of specified chemicals, including phthalates, from products purchased in retail stores. The references provided few or no details about all the materials used in the products, including whether other plastics were present, whether other component parts were present such as coatings, finishes, inks, or adhesives, or whether residues of the contained products were present.

The Task 12 Report also cited a Korean study of various products that reported low levels of phthalates in a toy car made with ABS. The study provided no details about other materials used in the product, including whether other plastics were present, or whether other component parts were present such as coatings, finishes, inks, or adhesives.

The Task 12 Report's detailed description of the raw materials and manufacturing processes for PP, PE, HIPS, and ABS plastics showed that phthalates are not present after these plastics are produced. However, the Task 11 Report describes uses of phthalates in materials on these plastics, such as coatings, inks, and adhesives. Because consumer products purchased in stores likely consist of a number of different component parts, some of which may have contained phthalates, the studies described above should not be considered to be evidence that phthalates were used in the manufacture of the PP, PE, HIPS, or ABS plastic component parts of consumer products subject to the phthalate content restrictions.

8. Phthalates in Recycled Materials

All four plastics may be recycled and reprocessed into new products. However, degradation of the original plastics during the recycling process and mixing with other plastics or materials in the recycling steam can reduce the quality of the recovered plastic and limit further commercial uses. In some cases, recovered plastics are mixed with virgin plastics to improve the products' quality and utility. The Task 12 Report indicated that few studies were located for analysis of phthalates in recycled plastics. One study found no phthalates in recycled PP carpet. Two studies analyzed solid waste consisting of PP or PE. One study reported detection of phthalates in recovered waste PP and PE material, but not in samples of virgin PP or PE plastic. The other study reported phthalates in recovered PE. The authors of the latter study suggested that the source of phthalates could have been the products that had been in contact with the plastic.

HIPS and ABS are generally used as rigid materials; available information does not indicate use of phthalates in such materials or associated with recycled HIPS or ABS.

Some studies indicated the potential for low, but detectable, levels of phthalates in plastics, such as PP or PE packaging that contained or had been in contact with a phthalate-containing product. Products made with such materials could contain residual phthalates, although at levels well below the maximum allowed concentration in children's products.[12]

9. Staff Conclusions Based on TERA Research

With the exception of the catalysts for polymerization, and certain, specific uses of phthalates in products without consumer product applications, neither of the TERA task reports, nor research by CPSC staff found that phthalates are used as a component part of the four plastics. In the case of the phthalate catalysts used in plastics manufacturing, the phthalate concentration in finished plastics is significantly below the maximum allowable concentration.

The two TERA task reports and CPSC staff research show that very little information exists that indicates that manufactured PP, PE, HIPS, and ABS plastics could contain the researched phthalates. The research located references, including patents, for uncommon and specialized products, and products that generally do not have applications to children's toys and child care articles.

Staff found no evidence that phthalates are present at concentrations above 0.1 percent in any of the four plastics (either virgin or using recycled material) for consumer products, especially children's products.

D. Determinations for Specified Plastics

1. Legal Requirements for a Determination

As noted above, section 14(a)(2) of the CPSA requires third party testing for children's products that are subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Children's toys and child care articles must comply with the phthalates prohibitions in section 108 of the CPSIA. 15 U.S.C. 2057c. In response to statutory direction, the Commission has investigated approaches that would reduce the burden of third party testing while also assuring compliance with CPSC requirements. As part of that endeavor, the Commission has considered whether certain materials used in children's toys and child care articles would not require third party testing.

To issue a determination that a plastic (including specified additives) does not require third party testing, the Commission must have sufficient evidence to conclude that the plastic and specified additives would consistently comply with the CPSC requirement to which the plastic (and specified additives) is subject so that third party testing is unnecessary to provide a high degree of assurance of compliance. Under 16 CFR part 1107 section 1107.2, "a high degree of assurance" is defined as "an evidence-based demonstration of consistent performance of a product regarding compliance based on knowledge of a product and its manufacture."

For a material determination, a high degree of assurance of compliance means that the material will comply with the specified chemical limits due to the nature of the material or due to a processing technique that reduces the chemical concentration below its limit. For materials determined to comply with a chemical limit, the material must continue to comply with that limit if it is used in a children's product subject to that requirement. A material on which a determination has been made cannot be altered or adulterated to render it noncompliant and then used in a children's product.

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[12] The highest level recorded by Huber and Franz was 200 ppm for one sample of DBP. The other samples' concentrations ranged from 3.1 to 96.3 ppm.

Phthalates are not naturally occurring materials, but are intentionally created and used in specific applications (*e.g.,* plastics, surface coatings, solvents, inks, adhesives, and some rubberized materials). One application of phthalates in children's toys and child care articles is as a plasticizer, or softener for plastic component parts.[13] The addition of a plasticizer converts an otherwise rigid plastic into a more flexible form, such as in a child's rubber duck or a soft plastic doll. Because plastics can contain the prohibited phthalates, third party testing is required before a CPC can be issued for children's toys and child care articles with accessible plastic component parts. However, some specific plastics with certain additives might not use any of the prohibited phthalates as a plasticizer, or for any other purpose. For these specific plastics and accompanying additives, compliance with the requirements of section 108 of the CPSIA can be assured without requiring third party testing. As a means to reduce the third party testing burden on children's product certifiers while continuing to ensure compliance, the CPSC is proposing to make determinations that specified plastics with certain additives comply with the phthalate content requirements of section 108 of the CPSIA based on evidence indicating that such materials will not contain the prohibited phthalates.

Based on the discussion in section C of this preamble, the Commission proposes to determine that the specified four plastics and accompanying additives would comply with the phthalates prohibitions with a high degree of assurance. These determinations mean that third party testing for compliance with the phthalates prohibitions is not required for certification purposes for the specified four plastics. The Commission proposes to make these determinations to reduce the third party testing burden on children's product certifiers while continuing to assure compliance.

2. Statutory Authority

Section 3 of the CPSIA grants the Commission general rulemaking authority to issue regulations, as necessary, to implement the CPSIA. Public Law 110–314, sec. 3, Aug. 14, 2008. As noted previously, section 14 of the CPSA, which was amended by the CPSIA, requires third party testing for children's products subject to a children's product safety rule. 15 U.S.C. 2063(a)(2). Section 14(d)(3)(B) of the CPSA, as amended by Public Law 112–28, gives the Commission the authority to "prescribe new or revised third party testing regulations if it determines that such regulations will reduce third party testing costs consistent with assuring compliance with the applicable consumer product safety rules, bans, standards, and regulations." *Id.* 2063(d)(3)(B). These statutory provisions authorize the Commission to issue a rule determining that specified plastics and additives will not exceed the phthalates prohibitions of section 108 of the CPSIA, and therefore, specified plastics do not require third party conformity assessment body testing to assure compliance with the phthalates limits in section 108 of the CPSIA.

The proposed determinations would relieve the four specified plastics and accompanying additives from the third party testing requirement of section 14 of the CPSA for purposes of supporting the required certification. However, the proposed determinations would not be applicable to any other plastic or additives beyond those listed in the proposed rule.

The proposed determinations would only relieve the manufacturers' obligation to have the specified plastics and accompanying additives tested by a CPSC accepted third party conformity assessment body. Children's toys and child care articles must still comply with the substantive phthalates content limits in section 108 of the CPSIA regardless of any relief on third party testing requirements.

3. Description of the Proposed Rule

This proposed rule would create a new Part 1308 for "Prohibition of Children's Toys and Child Care Articles Containing Specified Phthalates: Determinations Regarding Certain Plastics." The proposed rule would determine that the specified four plastics and accompanying additives do not contain the statutorily prohibited phthalates (DEHP, DBP, BBP, DINP, DIDP, DnOP) in concentrations above 0.1 percent, and thus, are not required to be third party tested to assure compliance with section 108 of the CPSIA. As discussed in section A.2 of the preamble, the agency is currently involved in rulemaking to determine whether to continue the interim prohibitions in section 108 and whether to prohibit any other children's products containing any other phthalates. TERA's examination covered all phthalates that are subject to the current permanent and interim prohibitions, as well as the additional phthalates the Commission proposed restricting in the phthalates proposed rule. If the Commission issues a final rule in the phthalates rulemaking before finalizing this determinations rulemaking, the Commission would modify the determinations proposed rule so that the determinations rule covers the same phthalates restricted by the final phthalates rule.

Section 1308.1 of the proposed rule explains the statutorily-created requirements for children's toys and child care articles under section 108 of the CPSIA and the third party testing requirements for children's products.

Section 1308.2(a) of the proposed rule would establish the Commission's determinations that the following plastics do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

- Polypropylene, with any of the following additives:
  - the plasticizers polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, mineral plasticizing oils, and polyol;
  - hydrocarbon solvents;
  - catalysts;
  - fillers;
  - nucleating agents;
  - primary and secondary antioxidants;
  - neutralizing agents;
  - antistatic agents;
  - slip agents;
  - metal deactivators;
  - quenchers;
  - UV stabilizers;
  - flame retardants;
  - blowing or foaming agents;
  - antiblocking agents;
  - lubricants; or
  - colorants.
- Polyethylene, with any of the following additives:
  - the plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;
  - catalysts;

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[13] The Merriam-Webster online dictionary defines a plasticizer as "a chemical added especially to rubbers and resins to impart flexibility, workability, or stretchability."

  - initiators;
  - promoters;
  - antistatic agents;
  - fillers;
  - flame retardants;
  - anti-blocking agents;
  - slip agents;
  - blowing agents;
  - cross-linking agents;
  - antioxidants;
  - carbon black; or
  - colorants.
- High-impact polystyrene, with any of the following additives:
  - catalysts;
  - internal lubricants;
  - chain transfer/transition agents;
  - stabilizers;
  - diluents;
  - colorants;
  - aluminum chloride, ethyl chloride, hydrochloric acid;
  - iron oxide, potassium oxide, chromium oxide; or
  - bifunctional peroxides.
- Acrylonitrile butadiene styrene, with any of the following additives:
  - the plasticizers phosphate esters, long chain fatty acid esters and aromatic sulfonamide;
  - hydrocarbon solvents;
  - stabilizers;
  - lubricants;
  - antioxidants;
  - molecular weight regulators;
  - initiators/catalysts,
  - activators;
  - emulsifiers; or
  - colorants.

Section C.2 of the preamble provides a more detailed discussion of the additives for each of the four plastics with the specified additives including definitions of the additives and various examples of the types of additives.

Section 1308.2(b) of the proposed rule states that accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives listed in paragraph (a) of that section, are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Proposed § 1308.2(b) is included in the rule to make clear that when the listed plastics and accompanying additives are used in children's toys and child care articles, manufacturers and importers are not required to conduct the third party testing required in section 14(a)(2) of the CPSA and 16 CFR part 1107. Section 1308.2(c) of the proposed rule states that accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Proposed § 1308.2(c) is intended to make clear that if a manufacturer or importer uses any other plastic or additive in a children's toy or child care article not listed in proposed § 1308.1(a), that children's toy or child care article must be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107. Finally, the determinations in proposed § 1308.2(a) would only remove the obligation to have children's toys and child care articles tested by a third party conformity assessment body. Regardless of any third party testing relief that the proposed rule would provide, the manufacturer or importer must still comply with the underlying phthalates content prohibitions in section 108 of the CPSIA.

E. Effective Date

The Administrative Procedure Act (APA) generally requires that a substantive rule must be published not less than 30 days before its effective date. 5 U.S.C. 553(d)(1). Because the proposed rule would provide relief from existing testing requirements under the CPSIA, the Commission proposes a 30 day effective date for the final rule.

F. Regulatory Flexibility Act

1. Introduction

The Regulatory Flexibility Act (RFA) requires that agencies review a proposed rule for the rule's potential economic impact on small entities, including small businesses. Section 603 of the RFA generally requires that agencies prepare an initial regulatory flexibility analysis (IRFA) and make the analysis available to the public for comment when the agency is required to publish a notice of proposed rulemaking, unless the agency certifies that the NPR will not have a significant economic impact on a substantial number of small entities. The IRFA must describe the impact of the proposed rule on small entities and identify any alternatives which accomplish the statutory objectives and may reduce the significant economic impact of the proposed rule on small entities. Specifically, the IRFA must contain:

- A description of the reasons why action by the agency is being considered;
- a succinct statement of the objectives of, and legal basis for, the proposed rule;
- a description of, and where feasible, an estimate of the number of small entities to which the proposed rule will apply;
- a description of the projected reporting, recordkeeping, and other compliance requirements of the proposed rule, including an estimate of the classes of small entities subject to the requirements and the types of professional skills necessary for the preparation of reports or records; and
- an identification, to the extent possible, of all relevant federal rules which may duplicate, overlap, or conflict with the proposed rule.

2. Reason for Agency Action and Legal Basis for the Proposed Rule

The Commission is proposing this NPR to reduce the burden of third party testing on toy and child care article manufacturers, especially the burden on those that are small entities. Based on an extensive literature review seeking information on the raw materials used in the manufacture of the specified plastics, the worldwide manufacturing practices of the plastics, the typical applications, and the potential for exposure to the specified phthalates through the use of recycled materials or due to contamination, the Commission concludes that there is a high degree of assurance that polypropylene, polyethylene, high impact polystyrene, and acrylonitrile butadiene styrene with the accompanying additives in the proposed rule will not contain any of the prohibited phthalates in concentrations above 0.1 percent when used in children's toys and child care articles. Therefore, third party testing is not necessary to assure that children's toys and child care articles with accessible component parts made from these plastics and accompanying additives do not contain the prohibited phthalates.

3. Small Entities To Which the Proposed Rule Would Apply

The proposed rule would apply to small entities that manufacture or import children's toys or child care articles that contain accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile butadiene styrene and any accompanying additives in component parts. Toy manufacturers are classified in North American Industry Classification System (NAICS) category 33993 ("Doll, Toy, and Game Manufacturing"). According to the U.S. Bureau of the Census, in 2012 there were 559 toy manufacturers in the United States, of which 552 had fewer than 500 employees and would be considered small entities according to the Small Business Administration (SBA) criteria.[14] Of the small manufacturers, 326 had fewer than five employees.

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[14] 2012 County Business Patterns.

Toy importers may be either wholesale merchants or retailers. The proposed rule would not apply to toy wholesalers or retailers if they obtain their merchandise from domestic manufacturers or importers. Toy wholesalers are classified in NAICS category 42392 ("Toy and Hobby Goods and Supplies Merchant Wholesalers"). According to the U.S. Bureau of the Census, there were 2,096 firms in this category.[15] Of these, 2,021 had fewer than 100 employees and would be considered small businesses according to SBA criteria. Toy retailers are classified in NAICS category 45112 ("Hobby, Toy, and Game Stores"). There could be about 5,800 toy retailers that would meet the SBA criteria to be considered a small entity.[16] The number of these small toy retailers that import toys, as opposed to obtaining their product from domestic sources is not known.

The phthalate regulations also apply to manufacturers and importers of child care articles. Child care articles include many types of products for which the CPSC has recently promulgated or proposed new or amended mandatory safety standards. These include toddler beds, full size and non-full size cribs, bassinets and cradles, bedside sleepers, high chairs, hook-on-chairs, and booster seats. Other child care articles include sleepwear, and crib or cradle bumpers. In its ongoing market research, CPSC staff has identified 364 suppliers of these products that would be considered small according to criteria established by the SBA. Additionally, there could be other child care articles, not listed above, for which CPSC has not yet developed a mandatory or proposed standard, but which nevertheless are covered by the phthalate requirements.

Child care articles would also include products such as teethers (if they are not medical devices), pacifiers, and bottle nipples. Manufacturers of these products are classified in NAICS category 326299 ("All other rubber product manufacturing"). There are 617 firms classified in this NAICS code of which 573 are considered to be small.[17] However, this NAICS category includes many other products and most of these firms probably do not manufacture child care articles.

Although, as discussed above, the number of small companies that supply children's toys or child care articles to the U.S. market might be close to 10,000, the number that actually supply products with accessible polyethylene, polypropylene, high impact polystyrene, or acrylonitrile, butadiene styrene component parts is not known. Also not known is the number of children's toys and child care articles that contain these plastics. To develop comprehensive estimates of the number of products that contain these plastics and the number of firms that supply the products it would probably be necessary to survey a representative sample of toy and child care article suppliers to solicit information on their use of the four plastics or to collect a representative sample of children's toys and child care articles and analyze the accessible components to determine which ones contained one or more of the four plastics.

Although comprehensive estimates of the number of children's toys and child care articles that contain components made from the four plastics are not available, there is some evidence that these plastics are extensively used in children's toys. One source stated that polypropylene and high density polyethylene are used in 38 and 25 percent, respectively, of injection molded toys. Low density polyethylene and acrylonitrile butadiene styrene, are each used in less than 10 percent of the injection molded toys. Polystyrene may also be used in injection molded toys, but the source does not specify the proportion that is high impact polystyrene.[18] The Commission requests comments to better determine the impact the proposed determinations would have on small entities.

4. Reporting, Recordkeeping, and Other Compliance Requirements and Impact on Small Businesses

The proposed rule would determine that there is a high degree of assurance that four specific plastics with any of the accompanying additives will not contain any prohibited phthalates at concentrations above 0.1 percent prohibition level. As a result of the proposed determinations, manufacturers, importers, and private labelers of children's toys and child care articles that have accessible components that consist of these plastics and any accompanying additives will not have to obtain third party tests to certify that the accessible components do not contain the prohibited phthalates in concentrations above 0.1 percent.

The proposed rule would not impose any additional reporting, recordkeeping, or other compliance requirements on small entities. In fact, because the proposed rule would eliminate a testing requirement, there would be a small reduction in some of the recordkeeping burden under 16 CFR part 1107 and 16 CFR part 1109 because manufacturers would no longer have to maintain records of third party phthalate tests for the component parts manufactured from these four plastics.

A determination that specified plastics with accompanying additives used in children's toys and child care articles do not require third party testing is expected to be entirely beneficial to manufacturers and importers using those plastics in accessible component parts because manufacturers and importers could forego testing they otherwise would be required to conduct. However, staff believes the magnitude of that benefit is uncertain and could depend on factors such as:

- The extent to which manufacturers have already reduced their testing costs by using component part testing (as allowed in 16 CFR part 1109);
- the volume of children's toys and child care articles that contain PE, PP, HIPS, or ABS;
- whether importers who certify children's products are unsure what plastics are being used in the toys and child care articles they import, so they could not take advantage of the determinations without additional testing to assure that a component part is composed of one of the four plastics.

The Commission welcomes comments on the potential impact of the proposed rule on small entities. Comments are especially welcome on the following topics:

- The extent to which PP, PE, HIPS, or ABS are used in children's toys and child care articles, especially those manufactured or imported by small firms;
- The potential reduction in third party testing costs that might be provided by the Commission making the determinations, including the extent to which component part testing is already being used;

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[15] 2012 County Business Patterns.

[16] The SBA considers a toy retailer (NAICS 45112) to be a small entity if its annual sales are less than $27.5 million. According to the U.S. Bureau of the Census, in 2007, the average receipts for toy manufacturers with more than 500 employees was almost $500 million. The average receipts for the next largest category for which summary data was published, toy retailers with at least 100 but fewer than 500 employees were about $12 million. There were 5,864 firms in this NAICS category, of which 5,839 had fewer than 500 employees. (U.S. Census Bureau, Number of Firms, Number of Establishments, Employment, Annual Payroll, and Estimated Receipts by Enterprise Employment Size for the United States, All Industries: 2007.)

[17] U.S. Bureau of the Census, "Number of Firms, Number of Establishments, Employment, and Annual Payroll by Enterprise Employment Size for the United States, All Industries: 2011," 2011 County Business Patterns.

[18] Donald V. Rosato, *Plastics End Use Applications,* Springer, New York, (2011).

- Any situations or conditions in the proposed rule that would make it difficult to make use of the determinations to reduce third party testing costs; and
- Although the Commission expects that the impact of the proposed rule will be entirely beneficial, any potential negative impacts of the proposed rule.

5. Other Federal Rules

We have not identified any Federal rules that duplicate or conflict with the proposed rule.

6. Alternatives Considered To Reduce the Burden on Small Entities

Under section 603(c) of the RFA, an initial regulatory flexibility analysis should "contain a description of any significant alternatives to the proposed rule which accomplish the stated objectives of the applicable statutes and which minimize any significant impact of the proposed rule on small entities." Because the proposed rule is intended to reduce the cost of third party testing on small businesses and will not impose any additional burden, the Commission did not consider alternatives to the proposed rule that would reduce the burden of this rule on small businesses.

G. Environmental Considerations

The Commission's regulations provide a categorical exclusion for Commission rules from any requirement to prepare an environmental assessment or an environmental impact statement because they "have little or no potential for affecting the human environment." 16 CFR 1021.5(c)(2). This rule falls within the categorical exclusion, so no environmental assessment or environmental impact statement is required. The Commission's regulations state that safety standards for products normally have little or no potential for affecting the human environment. 16 CFR 1021.5(c)(1). Nothing in this rule alters that expectation.

List of Subjects in 16 CFR Part 1308

Business and industry, Consumer protection, Imports, Infants and children, Product testing and certification, Toys.

■ Accordingly, the Commission proposes to amend Title 16 of the Code of Federal Regulations by adding part 1308 to read as follows:

PART 1308—PROHIBITION OF CHILDREN'S TOYS AND CHILD CARE ARTICLES CONTAINING SPECIFIED PHTHALATES: DETERMINATIONS REGARDING CERTAIN PLASTICS

Sec.

1308.1 Prohibited children's toys and child care articles containing specified phthalates and testing requirements.
1308.2 Determinations for specified plastics.

Authority: Sec. 3, Pub. L. 110–314, 122 Stat. 3016; 15 U.S.C. 2063(d)(3)(B).

§ 1308.1 Prohibited children's toys and child care articles containing specified phthalates and testing requirements.

Section 108(a) of the Consumer Product Safety Improvement Act of 2008 (CPSIA) permanently prohibits any children's toy or child care article that contains concentrations of more than 0.1 percent of di-(2-ethylhexl) phthalate (DEHP), dibutyl phthalate (DBP), or benzyl butyl phthalate (BBP). Section 108(b)(1) of the CPSIA prohibits on an interim basis any children's toy that can be placed in a child's mouth or child care article that contains concentrations of more than 0.1 percent of diisononyl phthalate (DINP), diisodecyl phthalate (DIDP), or di-n-octyl phthalate (DnOP). Materials used in children's toys and child care articles subject to section 108(a) and (b)(1) of the CPSIA must comply with the third party testing requirements of section 14(a)(2) of the Consumer Product Safety Act (CPSA), unless listed in § 1308.2.

§ 1308.2 Determinations for specified plastics.

(a) The following plastics do not exceed the phthalates content limits with a high degree of assurance as that term is defined in 16 CFR part 1107:

(1) Polypropylene (PP), with any of the following additives:

(i) The plasticizers polybutenes, dioctyl sebacate, paraffinic oil, isooctyl tallate, mineral plasticizing oils, and polyol;
(ii) Hydrocarbon solvents;
(iii) Catalysts;
(iv) Fillers;
(v) Primary and secondary antioxidants;
(vi) Neutralizing agents;
(vii) Antistatic agents;
(viii) Slip agents;
(ix) Metal deactivators;
(x) Quenchers;
(xi) UV stabilizers;
(xii) Nucleating agents;
(xiii) Flame retardants;
(xiv) Blowing or foaming agents;
(xv) Antiblocking agents;
(xvi) Lubricants; or
(xvii) Colorants.

(2) Polyethylene (PE), with any of the following additives:

(i) The plasticizers glyceryl tribenzoate, polyethylene glycol, sunflower oil, paraffin wax, paraffin oil, mineral oil, glycerin, EPDM rubber, and EVA polymer;
(ii) Initiators;
(iii) Promoters;
(iv) Catalysts;
(v) Fillers;
(vi) Antistatic agents;
(vii) Flame retardants;
(viii) Anti-blocking agents;
(ix) Slip agents;
(x) Blowing agents;
(xi) Ccross-linking agents;
(xii) Antioxidants;
(xiii) Carbon black; or
(xiv) Colorants.

(3) High-impact polystyrene (HIPS), with any of the following additives:

(i) Catalysts;
(ii) Internal lubricants;
(iii) Chain transfer/transition agents;
(iv) Stabilizers;
(v) Diluents;
(vi) Colorants;
(vii) Aluminum chloride, ethyl chloride, hydrochloric acid;
(viii) Iron oxide, potassium oxide, chromium oxide; or
(ix) Bifunctional peroxides.

(4) Acrylonitrile butadiene styrene (ABS), with any of the following additives:

(i) The plasticizers phosphate esters, long chain fatty acid esters and aromatic sulfonamide;
(ii) Hydrocarbon solvents
(iii) Stabilizers;
(iv) Lubricants;
(v) Antioxidants;
(vi) Molecular weight regulators;
(vii) Initiators/catalysts,
(viii) Activators;
(ix) Emulsifiers; or
(x) Colorants.

(b) Accessible component parts of children's toys and child care articles made with the specified plastics, and specified additives, listed in paragraph (a) of this section are not required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

(c) Accessible component parts of children's toys and child care articles made with a plastic or additives not listed in paragraph (a) of this section are required to be third party tested pursuant to section 14(a)(2) of the CPSA and 16 CFR part 1107.

Dated: August 11, 2016.

Todd A. Stevenson,

Secretary, Consumer Product Safety Commission.

[FR Doc. 2016–19464 Filed 8–16–16; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[USCBP–2016–0011]

RIN 1515–AE11

Importations of Certain Vehicles and Engines Subject to Federal Antipollution Emission Standards

AGENCY: U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document proposes amendments to the U.S Customs and Border Protection (CBP) regulations relating to the importation into the United States of certain vehicles and engines subject to federal antipollution emission standards under the Clean Air Act (CAA). Compliance with these emission standards must be demonstrated to CBP by either filing, or retaining and producing upon request, the appropriate U.S. Environmental Protection Agency (EPA) declaration form or by establishing that the subject imports are exempt from this requirement. CBP is proposing to amend its regulations to harmonize the documentation requirements applicable to different classes of vehicles and engines that are subject to the CAA's emission standards. This document also proposes to permit the required EPA emission compliance forms to be filed with CBP electronically. CBP is proposing other non-substantive amendments to update regulatory citations and delete obsolete provisions. The proposed changes set forth in this document support consistency in the administration of CBP's vehicle and engine imports program. In addition, electronic filing of EPA declaration forms will support key modernization initiatives, expedite the entry and clearance process, enhance targeting and enforcement objectives, and connect CBP with partner government agencies and the trade community through a single window access point.

DATES: Comments on the proposed rule must be received on or before September 16, 2016.

ADDRESSES: You may submit comments, identified by docket number, by *one* of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments via docket number USCBP 2016–0011.
- *Mail:* Trade and Commercial Regulations Branch, Office of Trade, Regulations and Rulings, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC 20229–1177.

Instructions: All submissions received must include the agency name and docket number for this proposed rulemaking. All comments received will be posted without change to *http://www.regulations.gov,* including any personal information provided. For detailed instructions on submitting comments and additional information on the proposed rulemaking process, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.regulations.gov.* Submitted comments may also be inspected during regular business days between the hours of 9 a.m. and 4:30 p.m. at the Trade and Commercial Regulations Branch, Office of Trade, Regulations and Rulings, U.S. Customs and Border Protection, 90 K Street NE., 10th Floor, Washington, DC. Arrangements to inspect submitted comments should be made in advance by calling Joseph Clark at (202) 325–0118.

FOR FURTHER INFORMATION CONTACT: For questions related to the filing of EPA forms with CBP, please contact William Scopa, Partner Government Agencies Interagency Collaboration Division, Office of Trade, Customs and Border Protection, at *William.R.Scopa@cbp.dhs.gov.* For questions related to EPA's vehicle and engine imports program, please contact Holly Pugliese at *pugliese.holly@epa.gov.*

SUPPLEMENTARY INFORMATION:

Public Participation

Interested persons are invited to participate in this rulemaking by submitting written data, views, or arguments on all aspects of the proposed rule. CBP also invites comments that relate to the economic, environmental, or federalism effects that might result from this proposed rule. If appropriate to a specific comment, the commenter should reference the specific portion of the proposed rule, explain the reason for any recommended change, and include data, information, or authority that supports such recommended change.

Background

The Clean Air Act (CAA), as amended (42 U.S.C. 7401 *et. seq.*), is the comprehensive federal law that regulates air emissions from stationary and mobile sources. Section 203(a) of the CAA, 42 U.S.C. 7522, prohibits, *inter alia,* importation into the United States of new motor vehicles and new motor vehicle engines unless they are covered by a certificate of conformity as prescribed by regulation authorized by the CAA. Section 203(b)(2) of the CAA provides that a new motor vehicle or new motor vehicle engine offered for importation in violation of section 203(a) will be refused admission into the United States. In this situation, however, the Secretary of the Treasury and the Administrator of the U.S. Environmental Protection Agency (EPA) may, by joint regulation, provide for a deferred final determination as to admission and authorize delivery of the goods to the importer or consignee upon such conditions (including the furnishing of a bond) as may be deemed appropriate. Section 208 of the CAA, 42 U.S.C. 7542, provides that the Administrator of the EPA may require a manufacturer to produce, among other items, all records, files, and papers necessary to demonstrate compliance with applicable CAA provisions. Section 213(d) of the CAA, 42 U.S.C. 7547, requires that nonroad vehicle and engine standards be enforced in the same manner as those applicable to onroad vehicles and engines.

These statutory provisions are implemented in the CBP regulations at §§ 12.73 and 12.74 of title 19 of the Code of Federal Regulations (19 CFR 12.73 and 12.74). Section 12.73 provides for "[M]otor vehicle and engine compliance with Federal antipollution emission requirements." Corresponding EPA regulations for motor vehicles and engines are promulgated at 40 CFR parts 85 and 86. Section 12.74 provides for "[N]onroad and stationary engine compliance with Federal antipollution emission requirements." Corresponding EPA regulations for nonroad and stationary engine compliance are promulgated at 40 CFR parts 1033 through 1068.

EPA requires the submission of certain documents for purposes of compliance with the CAA. EPA makes available EPA Declaration Form 3520–1 for the importation of passenger vehicles, highway motorcycles, and their corresponding engines into the United States, and EPA Declaration Form 3520–21 for the importation of heavy-duty highway engines and nonroad engines (gas, diesel, marine, stationary) into the United States, including engines already installed in vehicles or equipment. Both forms can be found in fillable .pdf format on EPA's "Imports Program" Web site at *http://www.epa.gov/otaq/imports/forms-resources.htm.*

Current CBP Filing Requirements for Importations of Certain Vehicles and Engines Subject to Federal Antipollution Emission Standards

I. 19 CFR 12.73/EPA Declaration Form 3520–1

For importations that are covered by EPA Declaration Form 3520–1, existing § 12.73(i) of the CBP regulations (19 CFR 12.73(i)) requires importers to file the requisite information with CBP at the time of entry. An exemption from this requirement exists for motor vehicle imports that are covered by an EPA Certificate of Conformity (COC) which are labeled accordingly (*see* 19 CFR 12.73(b)(1)); for these vehicles, an importer does not have to file the EPA Declaration Form 3520–1 with CBP at the time of entry, nor is the importer required to prepare and retain the form as part of its recordkeeping obligations. Section 12.73(g) also exempts motor vehicles imported by diplomats, foreign military personnel, and nonresidents from applicable emission requirements on the condition that the vehicles are not to be resold in the United States, and provided diplomats and foreign military personnel meet applicable documentation requirements set forth in paragraph (i)(4) of this section. In all other instances, the form is required to be completed and filed with CBP at the time of entry.

II. 19 CFR 12.74/EPA Declaration Form 3520–21

For importations that are covered by EPA Declaration Form 3520–21, existing § 12.74(b) (19 CFR 12.74(b)) requires importers to prepare the form and keep it on file for a period of at least five years from the date of entry in accordance with § 163.4 (19 CFR 163.4). The form must be made available upon request by CBP. Unlike motor vehicle manufacturers subject to § 12.73 (19 CFR 12.73), manufacturers that import products covered by EPA Declaration Form 3520–21 are not exempt from preparing this form even if the subject goods are covered by an EPA COC; they are required to prepare EPA Declaration Form 3520–21 and keep it on file for a period of at least five years from the date of entry.

Explanation of Proposed Amendments to CBP Regulations

III. Harmonization of Filing Requirements Applicable to EPA Declaration Forms 3520–1 and 3520–21

In an effort to provide consistency in the administration of CBP's vehicle and engine imports program so that importers of both road vehicles and engines, as well as stationary and nonroad engines (including engines incorporated into vehicles or equipment), are subject to the same filing and recordkeeping requirements, CBP is proposing to conform the entry filing requirements applicable to the EPA Declaration Form 3520–21 to those that currently exist for EPA Declaration Form 3520–1. Specifically, CBP is proposing to amend 19 CFR 12.74(b) to require that importers of stationary, nonroad or heavy-duty highway engines (including engines incorporated into vehicles or equipment) file EPA Declaration Form 3520–21 at the time of entry, unless exempt. CBP is proposing to exempt an importer that manufactures nonroad or stationary engines, including engines incorporated into vehicles and equipment, from the requirement to file an EPA Declaration Form 3520–21 at the time of entry if that importer holds a valid EPA COC for those engines and the engines are labeled to show compliance with applicable emission requirements.

IV. Electronic Filing of EPA Declaration Forms 3520–1 and 3520–21

This document proposes to amend §§ 12.73 and 12.74 to permit the electronic filing of EPA Declaration Forms 3520–1 and 3520–21 to CBP in the Automated Commercial Environment (ACE) or to any other CBP-authorized electronic data interchange system. The EPA declaration forms may also still be filed with CBP in paper with a paper entry filing at the time of entry.

The electronic filing of these forms will support key modernization and compliance initiatives of the International Trade Data System, as established by section 405 of the Security and Accountability for Every (SAFE) Port Act of 2006, Public Law 109–347, 120 Stat. 1884, by utilizing a single portal system (ACE) for the collection and distribution of standard electronic import and export data required by participating Federal agencies. The electronic transmission to CBP of EPA declaration forms will automate and enhance the interaction between the EPA and CBP by facilitating electronic collection, processing, sharing, and review of requisite trade data and documents during the cargo import and export process. Electronic filing of these EPA declaration forms at the time of entry will provide for a quicker and more efficient clearance process and enhance CBP's ability to conduct targeting and enforcement of importation requirements. Electronic filing will also permit CBP to analyze and flag problems immediately, whereas paper filings result in an ad-hoc process that requires a physical inspection by a CBP or EPA inspector. CBP is of the view that requiring EPA Declaration Forms 3520–1 and 3520–21 to be filed with every appropriate entry (with the exception of certain importing manufacturers, as described above) will expedite the clearing of vehicles and engines that are compliant with applicable emissions requirements.

V. Other Proposed Changes

CBP is proposing other changes to §§ 12.73 and 12.74 to update regulatory citations, delete provisions that are no longer relevant, and provide non-substantive re-statements of existing regulatory text to enhance readability. CBP is also updating regulatory language to ensure that electronic filing can be accommodated. The proposed changes are described below:

- CBP is proposing to amend § 12.73(a) to reflect updated EPA regulatory citations and to provide a non-substantive re-statement of the existing regulatory text to enhance readability.
- This document proposes to remove § 12.73(c)(3) from the CBP regulations. Paragraph (c)(3) sets forth requirements for vehicles participating in EPA-approved catalytic converter or oxygen sensor control programs. EPA no longer has such programs.
- This document proposes to remove § 12.73(c)(4) from the CBP regulations. Paragraph (c)(4) pertains to vehicles of United States or foreign origin manufactured with a catalytic converter or oxygen sensor, or any previously imported vehicle subsequently modified with a catalytic converter or oxygen sensor. Under this provision, these vehicles are not considered to be in compliance with applicable emission requirements if used outside of the United States, Canada, Mexico, or other countries as EPA may designate, until the catalytic converter and/or oxygen sensor is replaced. This provision was intended to address vehicles that may have traveled to countries where only leaded fuel was available, which could have a detrimental effect on catalytic converters and/or oxygen sensors. Since leaded fuel is no longer available in

most countries, it is proposed to delete this provision.

- CBP is proposing amendments to § 12.73(d) that further clarify the role of an Independent Commercial Importer, re-designate "working" days as "business" days, and provide a re-statement of existing regulatory text for enhanced readability.
- CBP is proposing amendments to § 12.73(e), in the introductory paragraph and paragraph (e)(4), that enhance readability and clarify that motorcycles are "highway" vehicles.
- CBP is proposing to amend § 12.73(f) by requiring that the designated motor vehicles be "new" in order to conform to the EPA regulatory requirements set forth in 40 CFR 85.1709. CBP also proposes editorial changes to enhance readability.
- In § 12.73(g)(2), CBP is proposing to change the existing reference to paragraph "(i)(4)" to "(i)(6)" to reflect that provision's proposed redesignation.
- The proposed amendments to § 12.73(h) enhance readability, reflect updated regulatory citations, and remove the word "motor" from the introductory text and from the regulatory text in paragraph (h)(5) pertaining to racing cars.
- CBP is proposing to amend § 12.73(i) by adding new paragraphs that prescribe methods of filing the EPA declaration forms and set forth applicable recordkeeping requirements, and by redesignating existing paragraph (i)(4) as new paragraph (i)(6).
- CBP is proposing to amend existing § 12.73(i)(4), redesignated in this proposed rule as paragraph (i)(6), by removing the requirement that diplomats and foreign military personnel must submit the emission declarations specified in existing 19 CFR 12.73(i)(2) (redesignated as 19 CFR 12.73(i)(3) in this proposed rule) with their entry, a copy of the motor vehicle importer's official orders or the name of the embassy to which the importer is accredited, if applicable. Pursuant to 19 CFR 148.82, the baggage and effects of diplomatic, consular, and other privileged personnel representing foreign governments are admitted free of duty without the filing of an entry upon the request of the Department of State. As State Department policy is to require that importation occur through the DS–1504 ("Request for Customs Clearance of Merchandise") process and not through the entry process, it is proposed to amend existing § 12.73(i)(4)—redesignated as proposed 19 CFR 12.73(i)(6)—to no longer require the submission of emission documentation, official orders, or embassy information. Instead, it is proposed that a claim by diplomats and foreign military personnel for exemption from § 12.73(g)(2) emission requirements must be supported by a Department of State-approved form DS–1504 or its electronic equivalent.
- Section 12.73(m) is proposed to be amended to reflect updated EPA regulatory citations.
- CBP is proposing to amend §§ 12.73(j) and 12.74(c)(1) by adding language stating that bonds may be submitted to CBP electronically and may be filed by a surety.
- This document proposes to remove § 12.74(a)(1)–(3) from the CBP regulations as these paragraphs refer to obsolete EPA regulatory sections, and to add language clarifying the scope of the applicable EPA emission regulations.
- This document proposes to remove § 12.74(c)(3)(iv) from the CBP regulations. Paragraph (c)(3)(iv) prescribes precertification for vehicles, engines and equipment. This provision refers to obsolete requirements found in EPA regulation 40 CFR 89.611(b)(3) regarding Independent Commercial Importers. EPA will make conforming amendments to its regulations to delete this provision.
- CBP is proposing to amend § 12.74(c)(3) to add exemptions that conditionally allow for the importation of nonconforming vehicles, engines, and equipment. Exemptions for diplomatic and military personnel (40 CFR 1068.325(e)), partially complete engines (40 CFR 1068.325(f)), and delegated assembly (40 CFR 1068.325(g)) were codified in EPA regulations since changes were last made to 19 CFR 12.74(c)(3) and are being proposed to be added to 19 CFR 12.74(c)(3) to ensure consistency with EPA regulations.
- CBP is proposing editorial amendments to § 12.74(d) to enhance readability.

VI. Conforming Changes to EPA Regulations

EPA regulations at 40 CFR parts 85 and 1068 also contain provisions related to the importation of vehicles, engines, and equipment. To the extent necessary to reflect the changes to the CBP regulations proposed in this document, EPA will make conforming amendments to its regulations in a separate action.

Executive Orders 12866 and 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This rule is not a "significant regulatory action," under section 3(f) of Executive Order 12866. Accordingly, the Office of Management and Budget (OMB) has not reviewed this regulation.

Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et. seq.*), as amended by the Small Business Regulatory Enforcement and Fairness Act of 1996, requires agencies to assess the impact of regulations on small entities. A small entity may be a small business (defined as any independently owned and operated business not dominant in its field that qualifies as a small business per the Small Business Act); a small not-for-profit organization; or a small governmental jurisdiction (locality with fewer than 50,000 people).

This rule proposes modifications to the requirements for the submission of EPA Declaration Form 3520–21. Currently, importers are required to fill out the form, but are only required to submit it to CBP upon request. This proposed rule, if finalized, would require importers to file EPA Declaration Form 3520–21 with CBP at the time of entry, unless the importer is a manufacturer of nonroad or stationary engines, including engines incorporated into vehicles and equipment, and holds a valid EPA certificate of conformity for those engines and the engines are labeled to show compliance with applicable emission requirements. As this form is already complete at the time of entry, the cost of submitting it to CBP is negligible. This rule would also explicitly add electronic filing as an accepted method of form submission. Importers will still be able to file the form by paper if they so choose. This change will affect all importers who are covered by EPA Declaration Form 3520–21, including small importers. Therefore, it is likely to have an impact on a substantial number of small entities. However, the only costs to the public are the negligible costs of submitting the already completed form to CBP along with other required entry documents. These costs do not rise to the level of significance. Therefore, CBP certifies that this proposed rule will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

The collection of information contained in this proposed rule was previously reviewed and approved by OMB in accordance with the requirements of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507) under control numbers OMB 2060–0104 (EPA Declaration Form 3520–1, "Importation of Motor Vehicles and Motor Vehicle Engines Subject to Federal Air Pollution Standards"), OMB 2060–0320 (EPA Declaration Form 3520–21, "Importation of Engines, Vehicles and Equipment Subject to Federal Air Pollution Standards"), and OMB 1405–0105 (Department of State form DS–1504, "Request for Customs Clearance of Merchandise"). As importers are already required under existing regulations to complete the EPA declaration forms and either submit them to CBP or retain them in their records, and the burden estimates in the above-identified OMB approved information collection requests presume the forms are submitted to CBP, there are no new collections of information proposed in this document. In this regard, it is noted that although existing 19 CFR 12.73 does not expressly require the submission of the EPA Declaration Form 3520–1, it does require that the same information captured by that form be submitted to CBP. Similarly, shipments sent from abroad to foreign diplomatic or consular missions in the U.S., or their personnel, currently must be cleared by respondents submitting to CBP a Department of State-approved form DS–1504; therefore, this document does not impose any new collections of information by requiring the DS–1504 to be presented to CBP for purposes of claiming an exemption from emission documentation requirements.

Signing Authority

This proposed regulation is being issued in accordance with 19 CFR 0.1(a)(1) pertaining to the Secretary of the Treasury's authority (or that of his delegate) to approve regulations related to certain customs revenue functions.

List of Subjects in 19 CFR Part 12

Air pollution control, Customs duties and inspection, Entry of merchandise, Imports, Labeling, Reporting and recordkeeping requirements, Restricted merchandise, Vehicles.

Proposed Amendments to Part 12 of the CBP Regulations

For the reasons set forth in the preamble, CBP proposes to amend 19 CFR part 12 as set forth below:

PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12, and the specific authority citation for sections 12.73 and 12.74, continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States), 1624.

* * * * *

Sections 12.73 and 12.74 also issued under 19 U.S.C. 1484, 42 U.S.C. 7522, 7601;

* * * * *

■ 2. Revise the undesignated center heading preceding § 12.73 to read as follows:

Entry of Motor Vehicles, Engines, and Equipment Containing Engines Under the Clean Air Act, as Amended

■ 3. Section 12.73 is amended by:
■ a. Revising the section heading;
■ b. Revising paragraph (a);
■ c. Removing in paragraph (b)(1) the word "shall" and adding in its place the word "will"; removing the word "Customs" and adding in its place the term "CBP", and; removing the term "ICI's" and adding in its place the words, "Independent Commercial Importers";
■ d. Removing in paragraph (b)(2) the word "Customs" and adding in its place the term "CBP";
■ e. Removing paragraphs (c)(3) and (4);
■ f. Revising paragraphs (d), (e) introductory text, (e)(4), and (f);
■ g. Removing in paragraph (g)(2) the reference "(i)(4)" and adding in its place the reference "(i)(6)";
■ h. Removing in paragraph (h) introductory text the word "motor";
■ i. Removing in the first sentence of paragraph (h)(1) the word "Any" and adding in its place the words "A motor vehicle imported for repairs is any";
■ j. Removing in the first sentence of paragraph (h)(2) the word "Any" and adding in its place the words, "A test vehicle is any";
■ k. Removing in the first sentence of paragraph (h)(3) the word "Any" and adding in its place the words, "A prototype vehicle is any", in the second sentence, removing the word "shall" and adding in its place the word "will", and removing the words "paragraph (1)" and adding in its place the words "paragraph (l)";
■ l. Removing in the first sentence of paragraph (h)(4) the word "Any" and adding in its place the following words, "A display vehicle is any";
■ m. Revising paragraphs (h)(5) through (7);
■ n. Revising paragraphs (i) through (k);
■ o. Removing in paragraph (l) the word "shall" and adding in its place the word "will", and; removing the word "Customs" and adding in its place the word "CBP"; and
■ p. Revising paragraph (m).

The revisions read as follows:

§ 12.73 Importation of motor vehicles and motor vehicle engines.

(a) *Applicability of EPA requirements.* This section is ancillary to the regulations of the U.S. Environmental Protection Agency (EPA) issued under the Clean Air Act, as amended (42 U.S.C. 7401 *et seq.*), and found in 40 CFR parts 85, 86, 1036, 1037, and 1068. The EPA regulations should be consulted for more detailed information concerning EPA emission requirements. This section applies to imported motor vehicles; this section also applies to separately imported engines only if they will be installed in heavy-duty motor vehicles. All references in this section to "motor vehicles" include these heavy-duty engines. Nothing in this section should be construed as limiting or changing in any way the applicability of the EPA regulations.

* * * * *

(d) *Importation of vehicles by an Independent Commercial Importer (ICI).* An ICI is generally an importer that does not have a contract with a foreign or domestic motor vehicle manufacturer for distributing products into the United States market (*see* 40 CFR 85.1502). ICIs act independently of motor vehicle manufacturers, but are required to bring motor vehicles into compliance with all applicable emissions requirements found in 40 CFR part 86 and any other applicable requirements of the Clean Air Act. Before the vehicle is deemed to be in compliance with applicable emission requirements and finally admitted into the United States, the ICI must keep the vehicle in storage for a 15-business day period. This period follows notice to EPA of completion of the compliance work to give EPA the opportunity to conduct confirmatory testing and inspect the vehicle and records. The 15-business day period is part of the 120-day period in which an ICI must bring the vehicle into compliance with applicable emission requirements. A motor vehicle may also be conditionally admitted by an ICI if it meets the requirements in 40 CFR 85.1505 or 85.1509. Individuals and businesses not entitled to enter nonconforming motor vehicles may arrange for their importation through an ICI certificate holder. In these circumstances, the ICI will not act as an agent or broker for CBP transaction purposes unless it is otherwise licensed or authorized to do so.

(e) *Exemptions and exclusions from emission requirements based on age of vehicle.* The following motor vehicles may be imported by any person and do not have to be shown to be in compliance with emission requirements before they are entitled to admissibility:

* * * * *

(4) Highway motorcycles manufactured before January 1, 1978;

* * * * *

(f) *Exemption for exports.* A new motor vehicle intended solely for export to a country not having the same emission standards applicable in the United States is not required to be covered by an EPA certificate of conformity if both the vehicle and its container bear a label or tag indicating that it is intended solely for export. 40 CFR 85.1709.

* * * * *

(h) * * *

(5) *Racing cars.* A racing car is any vehicle that meets one or more of the criteria found at 40 CFR 85.1703(a), and that will not be registered or licensed for use on or operated on public roads or highways in the United States. *See also* 40 CFR 85.1511(e).

(6) *National security importations.* A national security importation includes any motor vehicle imported for purposes of national security by a manufacturer. 40 CFR 85.1511(c)(1), 85.1702(a)(2) and 85.1708; and

(7) *Hardship exemption.* A hardship exemption includes any motor vehicle imported by anyone qualifying for a hardship exemption. 40 CFR 85.1511(c)(2).

(i) *Documentation requirements*—(1) *Exception for certain companies that manufacture and import motor vehicles.* The special documentation requirements of this paragraph (i) do not apply to the importation of motor vehicles by the company that manufactures the motor vehicles if the motor vehicles are covered by a valid EPA Certificate of Conformity (COC) held by the manufacturer and the motor vehicles are labeled to show compliance with applicable emission requirements pursuant to paragraph (b)(1) of this section.

(2) *Release.* CBP will not release a motor vehicle from custody unless the importer has submitted all documents necessary to demonstrate compliance with all applicable laws and regulations.

(3) *Required EPA documentation.* Unless otherwise exempt, importers of motor vehicles must submit one of the following EPA declaration forms to CBP at the time of entry:

(i) For heavy-duty motor vehicle engines, whether they are installed in a vehicle or separately imported as loose engines, submit EPA Declaration Form 3520–21, "Importation of Engines, Vehicles, and Equipment Subject to Federal Air Pollution Regulations;"

(ii) For all other motor vehicles, submit EPA Declaration Form 3520–1, "Importation of Motor Vehicles and Motor Vehicle Engines Subject to Federal Air Pollution Regulations."

(4) *Filing method.* The EPA declaration forms required to be submitted to CBP pursuant to paragraph (i)(3) of this section may be filed with CBP electronically in the Automated Commercial Environment (ACE) or via any other CBP-authorized electronic data interchange system, or as a paper filing at the time of entry.

(5) *Recordkeeping.* Documents supporting the information required in EPA Declaration Form 3520–1 must be retained by the importer for a period of at least five (5) years in accordance with § 163.4 of this chapter and must be provided to CBP upon request.

(6) *Documentation for diplomatic or foreign military personnel exemption.* In order for a diplomat or foreign military personnel to claim an exemption pursuant to paragraph (g)(2) of this section, CBP must receive a Department of State-approved form DS–1504 ("Request for Customs Clearance of Merchandise") or its electronic equivalent.

(j) *Release under bond.* If an EPA declaration form filed in accordance with paragraph (i)(3) of this section states that the entry is being filed under circumstances described in either paragraphs (h)(1), (2), (3) or (4) of this section, the entry will be accepted only if the importer, consignee, or surety, as appropriate, files a bond containing the bond conditions set forth in § 113.62 of this chapter, or files a bond electronically in ACE or via any other CBP-authorized electronic data interchange system, for the production of an EPA document stating that the vehicle or engine is in conformity with Federal emission requirements. The importer or consignee must deliver to the port director documentation of EPA approval before the exemption expires, or before some later deadline specified by the port director based on good cause. If the EPA statement is not delivered to the port director within the specified period, the importer or consignee must deliver or cause to be delivered to the port director those vehicles which were released under a bond required by this paragraph. In the event that the vehicle or engine is not redelivered within five (5) days following the date the exemption expires or any later deadline specified by the port director, whichever is later, liquidated damages will be assessed in the full amount of the bond, if it is a single entry bond, or if a continuous bond is used, in the amount that would have been assessed under a single entry bond.

(k) *Notices of inadmissibility or detention.* If a motor vehicle is determined to be inadmissible before or after release from CBP custody, the importer or consignee will be notified in writing of the inadmissibility determination and/or redelivery requirement. However, if a motor vehicle cannot be released from CBP custody merely because the importer has failed to attach to the entry the documentation required by paragraph (i) of this section, the vehicle will be held in detention by the port director for a period not to exceed 30-calendar days after filing of the entry at the risk and expense of the importer pending submission of the missing documentation. An additional 30-calendar day extension may be granted by the port director upon application for good cause shown. If the requisite EPA declaration form required pursuant to paragraph (i)(3) of this section has not been filed within this deadline, which must not exceed 60 days from the date of entry, CBP will issue a notice of inadmissibility.

* * * * *

(m) *Prohibited importations.* The importation of motor vehicles other than in accordance with this section and the EPA regulations in 40 CFR parts 85, 86, 600, 1036, 1037, and 1068 is prohibited.

■ 4. Section 12.74 amended by:

■ a. Revising the section heading and paragraphs (a) through (d); and

■ b. In paragraph (e) removing the word "shall' and adding in its place the word "must".

The revisions read as follows:

§ 12.74 Importation of nonroad and stationary engines, vehicles, and equipment.

(a) *Applicability of EPA regulations.* The requirements governing the importation of nonroad and stationary engines subject to conformance with applicable emission standards of the U.S. Environmental Protection Agency (EPA) are contained in 40 CFR parts 1033 through 1068. These EPA regulations should be consulted for detailed information as to the admission requirements for subject nonroad and stationary engines. EPA emission regulations also apply to vehicles and equipment with installed engines and all references in this section to nonroad or stationary engines include the vehicles and equipment in which the engines are installed. Nothing in this section may be construed as limiting or changing in any way the applicability of the EPA regulations.

(b) *Documentation requirements*—(1) *Exception for certain companies that manufacture and import nonroad or stationary engines, including engines incorporated into vehicles and equipment.* The special documentation requirements of this paragraph (b) do not apply to the importation of nonroad or stationary engines, including engines incorporated into vehicles or equipment, by the company that manufactures the engines, provided that the engines are covered by a valid EPA Certificate of Conformity (COC) held by the importing manufacturer and bear the manufacturer's label showing such conformity and other EPA-required information.

(2) *Release.* CBP will not release engines, vehicles, or equipment from custody unless the importer has submitted all required documents to demonstrate that the engines, vehicles, or equipment meet all applicable requirements.

(3) *Required EPA documentation.* Importers of nonroad or stationary engines, including engines incorporated into vehicles and equipment, must submit EPA Declaration Form 3520–21, "Importation of Engines, Vehicles, and Equipment Subject to Federal Air Pollution Regulations," to CBP at the time of entry.

(4) *Filing method.* EPA Declaration Form 3520–21 may be filed with CBP electronically in the Automated Commercial Environment (ACE) or via any other CBP-authorized electronic data interchange system, or as a paper filing at the time of entry.

(5) *Recordkeeping.* Documents supporting the information required in EPA Declaration Form 3520–21 must be retained by the importer for a period of at least five (5) years in accordance with § 163.4 of this chapter and must be provided to CBP upon request.

(c) *Release under bond*—(1) *Conditional admission.* If the EPA declaration form states that the entry for a nonconforming nonroad engine is being filed under one of the exemptions described in paragraph (c)(3) of this section, under which the engine may be conditionally admitted under bond, the entry will be accepted only if the importer, consignee, or surety, as appropriate, files a bond containing the bond conditions set forth in § 113.62(c) of this chapter, or files a bond electronically in ACE or via any other CBP-authorized electronic data interchange system, for the production of an EPA statement that the vehicle or engine is in conformity with Federal emission requirements.

(2) *Final admission.* Should final admission be sought and granted pursuant to EPA regulations for an engine conditionally admitted initially under one of the exemptions described in paragraph (c)(3) of this section, the importer or consignee must deliver to the port director the prescribed statement. The statement must be delivered within the period authorized by EPA for the specific exemption, or such additional period as the port director of CBP may allow for good cause shown. Otherwise, the importer or consignee must deliver or cause to be delivered to the port director the subject engine, either for export or other disposition under applicable CBP laws and regulations (*see* paragraph (e) of this section). If such engine is not redelivered within five (5) days following the allotted period, liquidated damages will be assessed in the full amount of the bond, if a single entry bond, or if a continuous bond, the amount that would have been assessed under a single entry bond (*see* 40 CFR 1068.335).

(3) *Exemptions.* The specific exemptions under which a nonconforming nonroad engine may be conditionally admitted, and for which a CBP bond is required, are as follows:

(i) Repairs or alterations (*see* 40 CFR 1068.325(a)).

(ii) Testing (*see* 40 CFR 1068.325(b)).

(iii) Display (*see* 40 CFR 1068.325(c)).

(iv) Export (*see* 40 CFR 1068.325(d)).

(v) Diplomatic or military (*see* 40 CFR 1068.325(e)).

(vi) Delegated assembly (*see* 40 CFR 1068.325(f)).

(vii) Partially complete engines, vehicles, or equipment (*see* 40 CFR 1068.325(g).

(d) *Notice of inadmissibility or detention.* If an engine is found to be inadmissible either before or after release from CBP custody, the importer or consignee will be notified in writing of the inadmissibility determination and/or redelivery requirement. If the inadmissibility is due to the fact that the importer or consignee did not file the EPA Declaration Form 3520–21 at the time of entry, the port director may hold the subject engine in detention at the importer's risk and expense for up to 30 days from the entry filing date. The port director may grant the importer's request for a 30-day extension for good cause. The port director will issue a notice of inadmissibility if documentation is still incomplete after this deadline, which must not exceed 60 days from the filing date for importation.

* * * * *

R. Gil Kerlikowske,
Commissioner.

Approved: August 3, 2016.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016–18761 Filed 8–16–16; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

25 CFR Part 30

[167A2100DD/AAKC001030/ A0A501010.999900 253G]

Notice of Intent To Establish a Negotiated Rulemaking Committee

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Extension of comment and nomination periods.

SUMMARY: On November 9, 2015, the Bureau of Indian Education (BIE) published a notice of intent requesting comments and nominations for Tribal representatives for the Accountability Negotiated Rulemaking Committee (Committee). The comment period for that notice of intent closed December 24, 2015. On April 14, 2016, the BIE reopened the comment and nomination period with a new deadline of May 31, 2016. The BIE is further extending the comment period for Tribes to nominate individuals for membership on the Committee. The BIE also solicits comments on the proposal to establish the Committee, including comments on additional interests not identified in this notice of intent and comments on the expansion of the scope of the Committee. The BIE is also correcting a drafting error in the April 14, 2016 Notice that omitted from Section III the central purpose of the Committee under the requirements of the Every Student Succeeds Act (ESSA), which requires the Secretary of the Interior, using a negotiated rulemaking process, to develop regulations for implementation no later than the 2017–2018 academic year. It also requires the Secretary to define the standards, assessments, and accountability system consistent with Section 1111 of the Elementary and Secondary Education Act (ESEA) for the schools funded by BIE on a national, regional, or tribal basis.

DATES: Submit nominations for Committee members or written comments on this notice of intent on or before October 3, 2016.

ADDRESSES: You may submit nominations for Committee members or written comments on this notice of intent to Ms. Jackie Cheek, Bureau of Indian Education, by any of the following methods:

- (Preferred method) Email to: *AYPcomments@bia.gov;*
- Mail, hand-carry or use an overnight courier service to Ms. Jackie Cheek, Bureau of Indian Education, 1849 C Street NW., Mail Stop 3642, Washington, DC 20240.

FOR FURTHER INFORMATION CONTACT: Ms. Jackie Cheek, Bureau of Indian Education; telephone: (202) 208–6983.

SUPPLEMENTARY INFORMATION:

I. Background

On November 9, 2015, BIE published a notice of intent requesting nominations for a negotiated rulemaking committee to recommend revisions to the existing regulations for BIE's accountability system (80 FR 69161). In that notice of intent, the BIE solicited nominations from Tribes whose students attend BIE-funded schools operated either by the BIE or by the Tribe through a contract or grant, to nominate Tribal representatives to serve on the Committee and Tribal alternates to serve when the representative is unavailable.

Since that time, the Every Student Succeeds Act (ESSA), Public Law 114–95, became law requiring an update to the subject, scope, and issues that the Committee will address. On April 14, 2016, BIE then announced its intent to expand the scope of the committee and reopened the comment and nomination period, requesting comments and nominations by May 31, 2016. 81 FR 22039 (April 14, 2016).

II. Every Student Succeeds Act (ESSA)

The ESSA reauthorizes and amends the Elementary and Secondary Education Act of 1965 (ESEA). ESSA Section 8007(2) directs the Secretary of the Interior, in consultation with the Secretary of Education, if so requested, to use a negotiated rulemaking process to develop regulations for implementation no later than the 2017–2018 academic year. The regulations will define the standards, assessments, and accountability system consistent with Section 1111 of the ESEA, for BIE-funded schools on a national, regional, or Tribal basis. The regulations will be developed in a manner that considers the unique circumstances and needs of such schools and the students served by such schools.

ESSA Section 8007(2) also provides that if a Tribal governing body or school board of a BIE-funded school determines the requirements established by the Secretary of the Interior are inappropriate, they may waive, in part or in whole, such requirements. Where such requirements are waived, the Tribal governing body or school board shall, within 60 days, submit to the Secretary of the Interior a proposal for alternative standards, assessments, and an accountability system, if applicable, consistent with ESEA Section 1111. The proposal must take into account the unique circumstances and needs of the school or schools and the students served. The proposal will be approved by the Secretary of the Interior and the Secretary of Education, unless the Secretary of Education determines that the standards, assessments, and accountability system do not meet the requirements of ESEA Section 1111. Additionally, a Tribal governing body or school board of a BIE-funded school seeking a waiver may request, and the Secretary of the Interior and the Secretary of Education will provide, technical assistance.

Due to the statutory changes described above, BIE expanded the scope of the negotiated rulemaking committee to receive recommendations and revise our current regulations (25 CFR part 30). This document provides notice that BIE is extending the comment period for: (1) Nominations of individuals for membership on the Committee and (2) comments on the proposal to establish the Committee, including comments on additional interests not identified in this notice of intent and comments on the expansion of the scope of the Committee.

III. The Committee and Its Process

The BIE encourages Tribal self-determination in Native education, encouraging Tribes to develop alternative standards, assessments, and an accountability system and providing technical assistance.

The negotiated rulemaking committee would be charged, consistent with ESSA Section 8007, with developing regulations, no later than the 2017–2018 academic year, for implementation of the Secretary's responsibility to define the standards, assessments, and an accountability system consistent with ESEA Section 1111, for schools funded by the BIE on a national, regional, or tribal basis, as appropriate, taking into account the unique circumstances and needs of such schools and the students served by such schools. Additionally, the Committee will be asked to provide recommendations that encourage the exercise of the authority of Tribes to adopt their own standards, assessments, and an accountability system and also to provide recommendations on how BIE could best provide technical assistance under ESSA Section 8007(2).

IV. Nominations

Each nomination is expected to include a nomination for a representative and an alternate who can fulfill the obligations of membership should the representative be unable to attend. The Committee membership should also reflect the diversity of Tribal interests, and Tribes should nominate representatives and alternates who will:

- Have knowledge of school assessments and accountability systems;
- Have relevant experience as past or present superintendents, principals, teachers, or school board members, or possess direct experience with Adequate Yearly Progress (AYP);
- Be able to coordinate, to the extent possible, with other Tribes and schools who may not be represented on the Committee;
- Be able to represent the Tribe(s) with the authority to embody Tribal views, communicate with Tribal constituents, and have a clear means to reach agreement on behalf of the Tribe(s);
- Be able to negotiate effectively on behalf of the Tribe(s) represented;
- Be able to commit the time and effort required to attend and prepare for meetings; and
- Be able to collaborate among diverse parties in a consensus-seeking process.

The BIE will consider nominations for Tribal committee representatives only if they are nominated through the process identified in this notice of intent and in the **Federal Register** notices of intent at 80 FR 69161 and 81 FR 22040. The BIE will not consider any nominations that it receives in any other manner. The BIE will not consider nominations for Federal representatives. Only the Secretary may nominate Federal employees to the Committee.

Based upon the proportionate share of students (see Section V of **Federal Register** notice of intent at 80 FR 69161), some Tribes similar in affiliation or geography are grouped together for one seat. It will be necessary for such nominating Tribes either to co-nominate a single Tribal representative to represent the multi-Tribal jurisdiction or for each Tribe in the multi-Tribal jurisdiction to nominate a representative with the knowledge that BIE will be able to appoint only one of the nominees who will then be responsible for representing the entire multi-Tribal jurisdiction on the Committee.

Nominations must include the following information about each nominee:

(1) A letter from the Tribe supporting the nomination of the individual to serve as a Tribal representative for the Committee;

(2) A resume reflecting the nominee's qualifications and experience in Indian education; resume to include the nominee's name, Tribal affiliation, job title, major job duties, employer, business address, business telephone and fax numbers (and business email address, if applicable);

(3) The Tribal interest(s) to be represented by the nominee (see Section IV, Part F of **Federal Register** notice of intent at 80 FR 69161) and whether the nominee will represent other interest(s) related to this rulemaking, as the Tribe may designate; and

(4) A brief description of how the nominee will represent Tribal views, communicate with Tribal constituents, and have a clear means to reach agreement on behalf of the Tribe(s) they are representing.

(5) A statement on whether the nominee is only representing one Tribe's views or whether the expectation is that the nominee represents a specific group of Tribes.

To be considered, nominations must be received by the close of business on the date listed in the **DATES** section, at the location indicated in the **ADDRESSES** section.

If you already submitted a nomination prior to the December 24, 2015, deadline or May 31, 2016 deadline, your application will still be considered.

V. Certification

For the above reasons, I hereby certify that the Accountability Negotiated Rulemaking Committee is in the public interest.

Dated: August 8, 2016.

Lawrence S. Roberts,

Principal Deputy Assistant Secretary—Indian Affairs.

[FR Doc. 2016–19599 Filed 8–16–16; 8:45 am]

BILLING CODE 4337–15–P

DEPARTMENT OF LABOR

Office of the Secretary

29 CFR Part 70

RIN 1290–AA30

Revision of the DOL FOIA Regulations

AGENCY: Office of the Secretary, Department of Labor.

ACTION: Notice of proposed rulemaking, request for comments.

SUMMARY: This rule proposes revisions to the Department of Labor's regulations under the Freedom of Information Act (FOIA), found in our regulations. The regulations are being revised to update and streamline the language of several procedural provisions, and to incorporate changes brought about by amendments to the FOIA under the OPEN Government Act of 2007 and the FOIA Improvement Act of 2016.

DATES: Written comments must be postmarked and electronic comments must be submitted on or before October 17, 2016. Comments received by mail will be considered timely if they are postmarked on or before that date. The electronic Federal Docket Management System (*https://www.regulations.gov*) will accept comments until Midnight Eastern Time at the end of that day.

ADDRESSES: You may submit comments by any of the following methods:

- *Federal eRulemaking Portal: https// www.regulations.gov.*
- *FAX:* (202) 693–5389. Send your comments to the attention of Ramona Branch Oliver.
- *Mail:* Ramona Branch Oliver, Director, Office of Information Services, MALS Division, Office of the Solicitor, U.S. Department of Labor, Suite N–2420, 200 Constitution Avenue NW., Washington, DC 20210.
- *E-mail: oliver.ramona@dol.gov.* Please indicate "Comments on FOIA Rule" in the subject line.
- To ensure proper handling, please reference Docket No. DOL–2016–007 on your correspondence.

FOR FURTHER INFORMATION CONTACT: Ramona Branch Oliver, Director, Office of Information Services, 202–693–5391.

Discussion: This rule proposes revisions to the Department's regulations under the FOIA, found at 29 CFR part 70, to update and streamline the language of several procedural provisions and to incorporate certain of the changes brought about by the amendments to the FOIA under the OPEN Government Act of 2007, Public Law 110–175, 121 Stat. 2524 and the FOIA Improvement Act of 2016, Public Law 114–185,130 Stat. 538 (enacted June 30, 2016). The Department of Labor last published FOIA regulations on May 30, 2006.

The proposed revisions to the Department's FOIA regulations in 29 CFR part 70 incorporate changes to the language and structure of the regulations. Revised provisions include § 70.1 (General provisions), § 70.2 (Definitions), § 70.3 (Policy), § 70.4 (Proactive disclosure of Department records), § 70.19 (Requirements for making a request), § 70.20 (Responsibility for responding to requests), § 70.21 (Responses to requests), § 70.25 (Time limits and order in which requests must be processed), § 70.38 (Definitions related to costs), and § 70.40 (Charges assessed for the production of records). Current sections have been renamed § 70.1 (from Purpose and scope to General provisions), § 70.4 (from Public reading rooms to Proactive disclosure of Departmental records), § 70.19 (from Requests for access to records to Requirements for making requests), § 70.21 (from Form and content of responses to Responses to requests), and § 70.26 (from Business information to Confidential commercial information). Also, in lieu of using the term "disclosure officer," DOL is using the word "component" to refer to the decentralized agency FOIA components throughout the draft regulation.

As the Department of Labor was completing preparation of this Notice of Proposed Rulemaking to update its FOIA regulation, Congress passed on June 13, 2016 and the President signed on June 30, 2016, the FOIA Improvement Act of 2016. The Department has incorporated changes to this proposed rule to address provisions of the FOIA Improvement Act of 2016. Specifically, the following sections of this NPRM were revised to reflect statutory changes: Section 70.1(d) and (f); Sec. 70.3; Sec. 70.4; Sec. 70.19(d); Sec. 70.21(d) and (e); Sec. 70.25(c); and Sec. 70.40(e). Comments on these proposed provisions based on the text of the amended statute are welcomed. The Department will consider those comments, along with any other comments received, and if appropriate will revise the regulation to ensure the rule aligns with the amended statute.

Regulatory Flexibility Act: The Secretary of Labor, in accordance with the Regulatory Flexibility Act (5 U.S.C. 605(b)), has reviewed this regulation and by approving it certifies that this regulation will not have a significant economic impact on a substantial number of small entities. Under the FOIA, agencies may recover only the direct costs of searching for, reviewing, and duplicating the records processed for requesters, and only for certain classes of requester and when particular conditions are satisfied. Thus, fees assessed by the Department are nominal. Further, the "small entities" that make FOIA requests, as compared with individual requesters and other requesters, are relatively few in number.

EO 12866: This regulation has been drafted and reviewed in accordance with Executive Order 12866, § 1(b), Principles of Regulation. The Office of Management and Budget has determined that this rule is not a "significant regulatory action" under Executive Order 12866, § 3(f), Regulatory Planning and Review, and accordingly this rule has not been reviewed by that Office.

Unfunded Mandates Reform Act of 1995: This rule will not result in the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1995: This rule is not a major rule as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (as amended), 5 U.S.C. 804. This rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 29 CFR Parts 70

Administrative practice and procedure; Freedom of Information Act; Privacy.

For the reasons stated in the preamble, the Department of Labor proposes to amend 29 CFR part 70, as follows:

PART 70—PRODUCTION OR DISCLOSURE OF INFORMATION OR MATERIALS

Subpart A—General

Sec.
70.1 General provisions.
70.2 Definitions.
70.3 Policy.
70.4 Proactive disclosure of Departmental records.
70.5 Compilation of new records.
70.6 Disclosure of originals.
70.7–70.18 [Reserved]

Subpart B—Procedures for Disclosure of Records Under the Freedom of Information Act

70.19 Requirements for making a request.
70.20 Responsibility for responding to requests.
70.21 Responses to requests.
70.22 Appeals from denial of requests.
70.23 Action on appeals.
70.24 Form and content of action on appeals.
70.25 Time limits and order in which requests and appeals must be processed.
70.26 Confidential commercial information.
70.27 Preservation of records.
70.28–70.37 [Reserved]

Subpart C—Costs for Production of Records

70.38 Definitions related to costs.
70.39 Statutes specifically providing for setting of fees.
70.40 Charges assessed for the production of records.
70.41 Reduction or waiver of fees.
70.42 Consent to pay fees.
70.43 Payment of fees.
70.44 Other rights and services.
70.45–70.52 [Reserved]

Subpart D—Public Records and Filings

70.53 Office of Labor-Management Standards.
70.54 Employee Benefits Security Administration.
Appendix A to Part 70—FOIA Components
Appendix B to Part 70—[Reserved]

Authority: 5 U.S.C. 301, 29 U.S.C. 551 *et seq.*, 5 U.S.C. 552, as amended; Reorganization Plan No. 6 of 1950, 5 U.S.C. Appendix, 29 U.S.C. 1026 (106), 5 U.S.C. app. 11., E.O. 12600, 52 FR 23781, 3 CFR, 1988 Comp., p. 235. This part also implements the public information provisions of the Labor-Management Reporting and Disclosure Act (LMRDA), 29 U.S.C. 435, see § 70.53 below; the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. 1026 (106), see § 70.54 below; and the Federal Advisory Committee Act (FACA), 5 U.S.C. app. 11, see § 70.40(i) below.

Subpart A—General

§ 70.1 General provisions.

(a) This part is organized as follows: subpart A contains general information about Department of Labor policies and procedures; subpart B sets forth the procedures for obtaining access to records of the Department; subpart C contains the Department's regulations on fees; and subpart D sets forth the procedures for obtaining access to certain public records. Appendix A contains a list of all Department of Labor FOIA components from whom records may be obtained.

(b) This part contains the rules that the Department of Labor follows in processing requests for records under the Freedom of Information Act (FOIA), as amended, 5 U.S.C. 552. The rules in this part should be read together with the text of the FOIA, which provides additional information about access to records maintained by the Department. Additionally, the Department's "Guide to Submitting Requests under the FOIA" and related documents contain helpful information about the specific procedures particular to the Department with respect to making FOIA requests, and descriptions of the types of records maintained by different components of the Department. These references are available at *http://www.dol.gov/dol/foia/guide6.html.*

(c) Requests made by individuals for records about themselves under the Privacy Act of 1974, 5 U.S.C. 552a, are processed under 29 CFR part 71 as well as under this part. Information routinely provided to the public as part of a regular Department activity (for example, press releases issued by the Office of Public Affairs (OPA)) may be provided to the public without following this subpart.

(d) As set forth in Sec. 70.3, the Department operates its FOIA program with a presumption of openness and withholds records or information under the FOIA only when the Department reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or when disclosure is prohibited by law.

(e) The Department has a decentralized system for processing requests, with each component handling requests for its own records. Each component has a FOIA Customer Service Center that can assist individuals in locating records and address questions regarding pending FOIA requests. A list of the Department's Customer Service Centers is available at *http://www.dol.gov/dol/foia/RequestorServiceCenters.htm.*

(f) The Secretary has designated a Chief FOIA Officer for the Department. Contact information for the Chief FOIA Officer is available on the Department's FOIA Web site, *http://www.dol.gov/dol/foia/.* The Office of Information Services (OIS), which is located within the Office of the Solicitor, provides Department level guidance and oversight for the Department's FOIA program and supports the statutorily-based responsibilities of the DOL Chief FOIA Officer.

(g) The Department has a designated FOIA Public Liaison who can assist individuals in locating records of a particular component and with resolving issues relating to the processing of a pending FOIA request. Information concerning the DOL FOIA Public Liaison is available at *http://www.dol.gov/sol/foia/liaison.htm.* The DOL FOIA Public Liaison is responsible for assisting in reducing delays in FOIA processing, increasing transparency and understanding, providing information concerning the status of requests, and assisting in the resolution of disputes.

§ 70.2 Definitions.

As used in this part:

(a) The terms agency, person, party, rule, order, and adjudication have the meaning attributed to these terms by the definitions in 5 U.S.C. 551.

(b) Confidential commercial information means commercial or financial information received or obtained by the Department from a submitter, directly or indirectly, that arguably may be protected from disclosure under Exemption 4 of the FOIA.

(c) The Department means the Department of Labor.

(d) FOIA Component means an official component of the Department that has authority to disclose or withhold records under the FOIA and to whom requests to inspect or copy records in its custody should be addressed. Department of Labor components are listed in Appendix A to this part.

(e) Record means any information that would be an agency record subject to the requirements of this part when maintained by an agency in any format, including an electronic format, and any information described under this part that is maintained for an agency by an entity under Government contract, for the purposes of records management.

(f) Request means any written request for records made pursuant to 5 U.S.C. 552(a)(3) and which meets the requirements of this part.

(g) Requester means any person who makes a request.

(h) Search means to look for, manually or by automated means, Department records for the purpose of locating them in response to a pending request.

(i) The Secretary means the Secretary of Labor.

(j) Submitter means any person or entity from whom the Department receives or obtains confidential commercial or financial information, directly or indirectly. The term submitter includes, but is not limited to corporations, labor organizations, non-profit organizations, and local, state, and tribal and foreign governments.

(k) Unusual circumstances means, to the extent reasonably necessary for the proper processing of a FOIA request:

(1) The need to search for and collect the requested records from physically separate facilities;

(2) The need to search for, collect, and appropriately examine a voluminous amount of separate and distinct records that are demanded in a single request; or

(3) The need for consultation, which will be conducted with all practicable speed, with another agency having a substantial interest in the determination of the request.

§ 70.3 Policy.

All agency records, except those exempt from mandatory disclosure by one or more provisions of 5 U.S.C. 552(b), will be made promptly available to any person submitting a written request in accordance with the procedures of this part. The Department will withhold records under the FOIA only when the Department reasonably foresees that disclosure would harm an interest protected by a FOIA exemption or is prohibited by law. Whenever the Department determines that full disclosure of a requested record is not possible, the Department will consider whether partial disclosure is possible and will take reasonable steps to segregate and release nonexempt material. As set forth in Sec. 70.4, the Department proactively identifies and discloses records of interest to the public.

§ 70.4 Proactive disclosure of Departmental records.

Records that are required by the FOIA, 5 U.S.C. 552 (a)(2), to be made available for public inspection in an electronic format may be accessed through the Department's Web site at *http://www.dol.gov/dol/foia/.* Each component is responsible for determining which of its records are required to be made publicly available, as well as identifying additional records of interest to the public that are appropriate for public disclosure, and for posting and indexing such records. Each component must review and update its Web site of posted records and indices on an ongoing basis.

§ 70.5 Compilation of new records.

Nothing in 5 U.S.C. 552 or this part requires that any agency or component create a new record in order to respond to a request for records. A component must, however, make reasonable efforts to search for records that already exist in electronic form or format, except when such efforts would significantly interfere with the operation of the component's automated information systems. The component will determine what constitutes a reasonable effort on a case-by-case basis.

§ 70.6 Disclosure of originals.

(a) No original record or file in the custody of the Department of Labor, or of any component or official thereof, will on any occasion be given to any agent, attorney, or other person not officially connected with the Department without the written consent of the Secretary, the Solicitor of Labor or the Inspector General.

(b) The individual authorizing the release of the original record or file must ensure that a copy of the document or file is retained in the component that had custody and/or control when an original document or file is released pursuant to this subpart.

§ 70.7–70.18 [Reserved]

Subpart B—Procedures for Disclosure of Records Under the Freedom of Information Act

§ 70.19 Requirements for making a request.

(a) General information. The Department of Labor has a decentralized system for responding to requests submitted under the FOIA. Each agency component has the ability to receive FOIA requests in writing by mail, delivery service/courier or facsimile at its designated mailing address. Any FOIA request submitted electronically, by email, must be submitted to *foiarequests@dol.gov.* Requests under this part submitted to any other email address will not be accepted.

(b) To make a request for records of the Department, whenever possible, a requester should write directly to the FOIA office of the component that maintains the records sought. Submitting the request directly to the FOIA office of the component that maintains the records sought will facilitate the quickest response. The requester must provide a mailing address to receive correspondence, and it may facilitate processing if telephone and email contact information are provided.

(1) The Department's components for the purposes of the FOIA are listed in Appendix A to this part. The function and mailing address of each Department of Labor component is available on the Department's FOIA Web site at *http://www.dol.gov/dol.foia.* This page also provides other information that is helpful in determining where to make a request.

(2) Requesters who cannot determine the proper FOIA office component or who are requesting records from multiple components may also send requests to the Office of the Solicitor, Office of Information Services, 200 Constitution Avenue NW., Room N–2420, Washington, DC 20210 or by email to *foiarequests@dol.gov.* Note that, pursuant to Sec. 70.25(a), the time for the component to respond to a request begins to run when the request is received by the proper component, but no later than 10 working days after

receipt in any component identified in Appendix A.

(c) Description of records sought. Requesters must describe the record or records sought in sufficient detail to enable Department personnel to locate them with a reasonable amount of effort. To the extent possible, the request should provide enough identifying information to help the component identify the requested records, such as the subject of the record, the date or approximate date when the record was created, the record's title or name, case or file number, reference number, the person or office or the office location that created it, and any other pertinent identifying details. Prior to submitting the request, a requester may wish to consult the references provided in Sec. 70.1, the relevant FOIA Requester Service Center or the FOIA Public Liaison to discuss the records they are seeking and to receive assistance on how to describe the records.

(d) Deficient descriptions and revised requests. If the description is insufficient, so that a knowledgeable employee who is familiar with the subject area of the request cannot identify the record with a reasonable amount of effort, the component processing the request will notify the requester and describe what additional information is needed to process the request.

(1) Requesters who are attempting to modify or reformulate their requests may discuss their requests with the component's designated FOIA contact, the FOIA Public Liaison, or a representative of OIS, each of whom is available to assist the requester in reasonably describing the records sought. Every reasonable effort will be made to assist a requester in the identification and location of the records sought. If the requester fails to reasonably describe the records sought, the agency's response to the request may be delayed.

(2) Any amended request must be confirmed in writing and meet the requirements for a request under this part.

(3) While an agency component awaits a requester's modified FOIA request, the processing time limits described in Sec. 70.25(a)(1) will be tolled (that is, the processing time clock will be stopped) until clarification is received from the requester.

§ 70.20 Responsibility for responding to requests.

(a) In general. Except in the instances stated in paragraph (d) of this section, the component that first receives a request for a record and maintains that record is the component responsible for responding to the request. In determining which records are responsive to a request, a component ordinarily will include only records in its possession as of the date that the component begins the search; if any other date is used, the component will inform the requester of that date. A record that is excluded from the requirements of the FOIA pursuant to 5 U.S.C. 552(c), is not considered responsive to a request. When it is determined that records responsive to a request may be located in multiple components of the Department, the Office of Information Services may coordinate the Department's response. If the Office of Information Services deems a consolidated response appropriate, it will issue such a response on behalf of the Department.

(b) Authority to grant or deny requests. Pursuant to relevant exemptions under 5 U.S.C. 552(b), the head of a component, or designee, is authorized to grant or to deny any requests for records that are maintained by that component.

(c) Re-routing of misdirected requests. Where a component's FOIA office determines that a request was misdirected within the Department, the receiving component's FOIA office will work with OIS to facilitate the routing of the request to the FOIA office of the proper component(s).

(d) Consultations and referrals. When a component receives a request for a record, it will determine if another component of the Department, or of the Federal Government, is better able to determine whether the record can be disclosed or is exempt from disclosure under the FOIA. If the receiving component determines that it is not best able to process the record, then the receiving component will either:

(1) Respond to the request after consulting with the component or agency best able to determine whether to disclose the record and with any other component or agency that has a substantial interest in the record; or

(2) Refer the responsibility for responding to the request regarding that record to the component best able to determine whether to disclose it, or to another agency that originated the record (but only if that entity is subject to the FOIA). Ordinarily, the component or agency that originated the record will be presumed to be best able to determine whether to disclose it.

(e) Notice of referral. Whenever a component refers all or any part of the responsibility for responding to a request to another component or agency, the component will notify the requester of the referral and inform the requester of the name of each component or agency to which the request has been referred and provide contact information for that component or agency.

(f) Classified records. Any request for classified records which are in the custody of the Department of Labor will be referred to the classifying agency under paragraphs (d) and (e) of this section.

§ 70.21 Responses to requests.

(a) In general. Components should, to the extent practicable, communicate with requesters using the method that is most likely to increase the speed and efficiency of the communication, including by electronic means, such as by email.

(b) Acknowledgements of requests. A component will acknowledge each new request and assign it an individualized tracking number. Components will include in the acknowledgment a brief description of the records sought to allow the requesters to more easily keep track of their requests.

(c) Granting a request. After a component makes a determination to grant a request in full or in part, the component will notify the requester in writing. The component will provide the record in the form or format requested if the record is readily reproducible in that form or format, provided the requester has agreed to pay and/or has paid any fees required by subpart C of this part. The component will determine on a case-by-case basis what constitutes a readily reproducible format. Each component should make reasonable efforts to maintain its records in commonly reproducible forms or formats.

(d) Adverse determinations of requests. A component making an adverse determination denying a request in any respect must notify the requester in writing. Adverse determinations, or denials of requests, include decisions that: the requested record is exempt, in whole or in part, from release pursuant to one or more exemptions under the FOIA, 5 U.S.C. 552; the request does not reasonably describe the records sought; the information requested is not a record subject to the FOIA; the requested record does not exist, cannot be located, or has been destroyed; or the requested record is not readily producible in the form or format sought by the requester. Adverse determinations also include denials involving fees or fee waiver matters or denials for requests for expedited processing.

(e) Content of the denial. The denial notice must be signed by the component agency head or a designee and will include:

(1) The name and title or position of the person responsible for the denial;

(2) A brief statement of the reason or reasons for the denial, including any FOIA exemption or exemptions applied or procedural reasons relied upon by the component in denying the request;

(3) An estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by the exemption under which the deletion was made;

(4) The right of the requester to seek assistance from the FOIA Public Liaison; and

(5) In the case of an adverse determination:

(i) a statement that the denial may be appealed as described under Sec. 70.22; and

(ii) a statement notifying the requester of the right to seek dispute resolution services from the Department's FOIA Public Liaison or the Office of Government Information Services (within the National Archives and Records Administration).

(f) Markings on released documents. Markings on released documents must be clearly visible to the requester. Records disclosed in part shall be marked to show the amount of information deleted and the exemption(s) under which the deletion was made unless doing so would harm an interest protected by an applicable exemption. The location of the information deleted shall also be indicated on the records, if technically feasible.

§ 70.22 Appeals from denial of requests.

(a) A requester may appeal to the Solicitor of Labor when one or more of the following has occurred: A request for access to records has been denied in whole or in part; a requester disputes a determination that records cannot be located or have been destroyed; a requester disputes a determination by a component concerning the assessment or waiver of fees; a requester disputes the denial of a request for expedited processing or a component fails to respond to a request within the time limits set forth in the FOIA. The appeal must be filed within 90 days of the date of the action being appealed.

(b) The appeal must state in writing the grounds for appeal, and it may include any supporting statements or arguments, but such statements are not required. In order to facilitate processing of the appeal, the appeal must include the assigned request number (if applicable), appellant's mailing address and daytime telephone number, as well as copies of the initial request and the component's response. If mailed, the envelope and the letter of appeal should be clearly marked: "Freedom of Information Act Appeal." Any amendment to the appeal must be in writing and received prior to a decision on the appeal.

(c) The appeal should be addressed to the Solicitor of Labor, Office of the Solicitor, FOIA Appeals Unit, Division of Management and Administrative Legal Services, U.S. Department of Labor, 200 Constitution Avenue NW., Room N–2420, Washington, DC 20210. Appeals also may be submitted by fax to 202–693–5538 or by email to *foiaappeal@dol.gov.* Appeals submitted to any other email address will not be accepted.

§ 70.23 Action on appeals.

The Solicitor of Labor, or designee, will review the appellant's appeal and make a determination de novo whether the action of the component was proper and in accordance with the applicable law.

§ 70.24 Form and content of action on appeals.

The disposition of an appeal will be issued by the Solicitor of Labor or designee in writing. A decision affirming, in whole or in part, the decision below will include a brief statement of the reason or reasons for the affirmance, including the FOIA exemption or exemptions relied upon, and its relation to each record withheld. Consistent with the statute, the appeal determination will also advise the requester of the availability of the mediation services of the Office of Government Information Services as a non-exclusive alternative to litigation, and the statutory right to judicial review of the denial by the United States District Court for the judicial district in which the requester resides or maintains his or her principal place of business, the judicial district in which the requested records are located, or the District of Columbia. If it is determined on appeal that a record should be disclosed, the record will be provided in accordance with the decision on appeal. If it is determined that records should be denied in whole or in part, the appeal determination will include an estimate of the volume of records or information withheld, in number of pages or in some other reasonable form of estimation. This estimate does not need to be provided if the volume is otherwise indicated through deletions on records disclosed in part, or if providing an estimate would harm an interest protected by an applicable exemption.

§ 70.25 Time limits and order in which requests and appeals must be processed.

(a) Time limits. The FOIA establishes a 20 business day deadline for regular requests and appeals, and a 10 calendar day time limit for making determinations regarding expedited processing. Components of the Department of Labor will comply with the time limits required by the FOIA for responding to and processing requests and appeals, unless there are exceptional circumstances within the meaning of 5 U.S.C. 552(a)(6)(C). A component or the designated appeal authority will notify a requester whenever they are unable to respond to or process the request or appeal within the time limits established by the FOIA.

(b) Multitrack processing. All components must designate a specific track for requests that are granted expedited processing, in accordance with the standards set forth in paragraph (d) of this section. A component may also designate additional processing tracks that distinguish between simple and complex requests based on the estimated amount of work and/or time needed to process the request, including based on the number of pages involved and the need for consultations or referrals. Components shall advise the requesters of the track into which their request falls and, when appropriate, shall offer the requester an opportunity to limit the scope of their requests in order to qualify for faster processing within the specified limits of the component's faster track.

(c) Unusual circumstances.

(1) Where the statutory time limits for processing a request cannot be met because of "unusual circumstances," as set forth in the FOIA at 5 U.S.C. 552(a)(6)(B)(i–iii), and the component determines to extend the time limits on that basis, the component shall, before the expiration of the 20 working day deadline to respond, notify the requester in writing of the unusual circumstances and of the date by which processing of the request can be expected to be completed. This extension should not ordinarily exceed ten business days. If the component intends to extend the

deadline to respond by more than ten working days, the component must:

(i) Provide the requester with an opportunity either to modify the request so that it may be processed within the time limits or to arrange an alternative time period with the component for processing the request or a modified request;

(ii) Make available to the requester the contact information for the designated FOIA contact and the FOIA Public Liaison to assist the requester; and

(iii) Notify the requester of the right to seek dispute resolution services from the Office of Government Information Services (OGIS).

(d) Aggregating requests. Where a component reasonably believes that multiple requests submitted by a requester, or by a group of requesters acting in concert, constitute a single request that would otherwise involve unusual circumstances, and the requests involve clearly related matters, they may be aggregated. Components shall not aggregate multiple requests involving unrelated matters.

(e) Expedited processing.

(1) Requests and appeals will be taken out of order and given expedited treatment whenever it is determined that they involve:

(i) Circumstances in which the lack of expedited treatment could reasonably be expected to pose an imminent threat to the life or physical safety of an individual;

(ii) An urgency to inform the public about an actual or alleged federal government activity, if made by a person primarily engaged in disseminating information;

(iii) The loss of substantial due process rights; or

(iv) A matter of widespread and exceptional media interest in which there exists possible questions about the government's integrity which affect public confidence.

(2) A request for expedited processing may be made at the time of the initial request for records or at any later time. For a prompt determination, a request for expedited processing must be received by the proper component. Requests based on paragraphs (e)(1)(i), (ii), (iii), and (iv) of this section must be submitted to the component that maintains the records requested.

(3) A requester who seeks expedited processing must submit a statement, certified to be true and correct to the best of that person's knowledge and belief, explaining in detail the basis for requesting expedited processing. For example, a requester within the category in paragraph (e)(1)(ii) of this section, if not a full-time member of the news media, must establish that he or she is a person whose main professional activity or occupation is information dissemination, though it need not be his or her sole occupation. Such a requester also must establish a particular urgency to inform the public about the government activity involved in the request—one that goes beyond the public's general right to know about government activity. The existence of numerous articles published on a given subject can be helpful in establishing the requirement that there be an "urgency to inform" the public on a topic. As a matter of administrative discretion, a component may waive the formality of certification.

(4) Within ten calendar days of its receipt of a request for expedited processing, the proper component will decide whether to grant the request and will notify the requester of the decision. If a request for expedited treatment is granted, the request will be given priority and will be processed as soon as practicable. If a request for expedited processing is denied, any appeal of that decision will be acted on expeditiously.

§ 70.26 Confidential commercial information.

(a) In general. Confidential commercial information will be disclosed under the FOIA only in accordance with this section and E.O. 12,600, "Predisclosure Notification Procedures for Confidential Commercial Information."

(b) Designation of confidential commercial information. A submitter of confidential commercial information will use good-faith efforts to designate, by appropriate markings, either at the time of submission or at a reasonable time thereafter, any portions of its submission that it considers to be protected from disclosure under Exemption 4. These designations will expire ten years after the date of the submission unless the submitter requests, and provides justification for, a longer designation period.

(c) Notice to submitters. A component will provide a submitter with prompt written notice of a FOIA request that seeks its confidential commercial information whenever required under paragraph (d) of this section, except as provided in paragraph (g) of this section, in order to give the submitter an opportunity to object in writing to disclosure of any specified portion of that information under paragraph (e) of this section. The notice will either describe the confidential commercial information requested or include copies of the requested records or record portions containing the information. When notification to a voluminous number of submitters is required, notification may be made by posting or publishing notice reasonably likely to accomplish such notification.

(d) When notice is required. Notice will be given to a submitter whenever:

(1) The information requested under the FOIA has been designated in good faith by the submitter as information considered protected from disclosure under Exemption 4; or

(2) A component has reason to believe that the information requested under the FOIA may be protected from disclosure under Exemption 4, but has not yet determined whether the information is protected from disclosure under that exemption or any other applicable exemption.

(e) Opportunity to object to disclosure. A component will allow a submitter a reasonable time to respond to the notice described in paragraph (c) of this section taking into account the amount of material the submitter has to review and the deadlines imposed by the FOIA or agreed to with the requester. If a submitter has any objection to disclosure, it is required to submit a detailed written statement. The statement must show why the information is a trade secret or commercial or financial information that is privileged or confidential. In the event that a submitter fails to respond to the notice within the time specified, the submitter will be considered to have no objection to disclosure of the information. Information provided by a submitter under this paragraph may itself be subject to disclosure under the FOIA.

(f) Notice of intent to disclose. A component will consider a submitter's timely objections and specific grounds for non-disclosure in deciding whether to disclose confidential commercial information. Whenever a component decides to disclose confidential commercial information over the objection of a submitter, the component will give the submitter written notice, which will include:

(1) A statement of the reason(s) why each of the submitter's disclosure objections were not sustained;

(2) A description of the confidential commercial information to be disclosed; and

(3) A specified disclosure date, which will be a reasonable time subsequent to the notice.

(g) Exceptions to notice requirements. The notice requirements of paragraphs (c) and (f) of this section will not apply if:

(1) The component determines that the information should not be disclosed;

(2) The information lawfully has been published or has been officially made available to the public;

(3) Disclosure of the information is required by statute (other than the FOIA) or by a regulation issued in accordance with the requirements of Executive Order 12,600 (3 CFR 1988 Comp., p. 235); or

(4) The designation made by the submitter under paragraph (b) of this section appears obviously frivolous or such a designation would be unsupportable—except that, in such a case, the component will, within a reasonable time prior to a specified disclosure date, give the submitter written notice of any final decision to disclose the information.

(h) Notice of a FOIA lawsuit. Whenever a requester files a lawsuit seeking to compel the disclosure of confidential commercial information, the component will promptly notify the submitter.

(i) Corresponding notice to requesters. Whenever a component provides a submitter with notice and an opportunity to object to disclosure under paragraphs (d) and (e) of this section, the component will also notify the requester(s). Whenever a component notifies a submitter of its intent to disclose requested information under paragraph (f) of this section, the component will also notify the requester(s). Whenever a submitter files a lawsuit seeking to prevent the disclosure of confidential commercial information, the component will notify the requester(s).

(j) Notice requirements. The component will fulfill the notice requirements of this section by addressing the notice to the confidential commercial submitter or its legal successor at the address indicated on the records, or the last known address. If the notice is returned, the component will make a reasonable effort to locate the confidential commercial submitter or its legal successor. Where notification of a voluminous number of submitters is required, such notification may be accomplished by posting and publishing the notice in a place reasonably calculated to accomplish notification.

§ 70.27 Preservation of records.

Each component will preserve all correspondence relating to the requests it receives under this part, and all records processed pursuant to such requests, until disposition or destruction of such correspondence and records is authorized by Title 44 of the United States Code or the National Archives and Records Administration's General Records Schedule 14. Records are not to be destroyed while they are the subject of a pending request, appeal, or lawsuit under the Act.

§ 70.28–70.37 [Reserved]

Subpart C—Costs for Production of Records

§ 70.38 Definitions related to costs.

The following definitions apply to this subpart:

(a) Request, in this subpart, includes any request, as defined by Sec. 70.2(f), as well as any appeal filed in accordance with Sec. 70.22.

(b) Direct costs means those expenditures which a component actually incurs in searching for and duplicating (and in the case of commercial use requests, reviewing) records to respond to a FOIA request. Direct costs include, for example, the salary of the Federal employee performing work (the basic rate of pay for the Federal employee plus 16 percent of that rate to cover benefits) and the cost of operating duplication machinery. Not included in direct costs are overhead expenses such as costs of space, heating or lighting the facility in which the records are kept.

(c) Reproduction means the process of making a copy of a record necessary to respond to a request. Such copy can take the form of paper, microform, audio-visual materials or electronic records (such as a CD or other media).

(d) Search means the process of looking for and retrieving records or information that is responsive to a FOIA request. It includes page-by-page or line-by-line identification of information within records and also includes reasonable efforts to locate and retrieve information from records maintained in electronic form or format. FOIA components will ensure that searches are done in the most efficient and least expensive manner reasonably possible. A search does not include the review of material, as defined in paragraph (e) of this section, which is performed to determine whether material is exempt from disclosure.

(e) Review means the process of examining records, including audio-visual, electronic mail, etc., located in response to a request to determine whether any portion of the located record is exempt from disclosure, and accordingly may be withheld. It also includes the act of preparing materials for disclosure, *i.e.,* doing all that is necessary to excise them and otherwise prepare them for release. Review time includes time spent contacting any submitter, and considering and responding to any objections to disclosure made by a submitter under Sec. 70.26, but does not include time spent resolving general legal or policy issues regarding the application of exemptions.

(f) Commercial use request means a request from or on behalf of a person who seeks information for a use or purpose that furthers his or her commercial, trade or profit interests, which can include furthering those interests through litigation. When considering fee issues, components will determine, whenever reasonably possible, the use to which a requester will put the requested records. When it appears that the requester will put the records to a commercial use, either because of the nature of the request itself or because a component has reasonable cause to doubt a requester's stated use, the component will provide the requester a reasonable opportunity to submit further clarification.

(g) Educational institution means an institution which:

(1) Is a preschool, public or private elementary or secondary school, an institution of undergraduate higher education, an institution of graduate higher education, an institution of professional education, or an institution of vocational education, or

(2) Operates a program or programs of scholarly research. To qualify under this definition, the program of scholarly research in connection with which the information is sought must be carried out under the auspices of the academic institution itself as opposed to the individual scholarly pursuits of persons affiliated with an institution. For example, a request from a professor for information that will assist in writing of a book, independent of his or her institutional responsibilities, would not qualify under this definition, whereas a request predicated upon research funding granted to the institution would meet its requirements. A request from a student enrolled in an individual course of study at an educational institution would not qualify as a request from the institution.

(h) Non-commercial scientific institution means an institution that is not operated on a commercial basis and that is operated solely for the purpose of conducting scientific research, the results of which are not intended to promote any particular product or industry.

(i) Representative of the news media means any person or entity that gathers information of potential interest to a segment of the public, uses its editorial skills to turn the raw materials into a distinct work, and distributes that work to an audience. Examples of news media entities include television or radio stations that broadcast "news" to the public at large and publishers of periodicals that disseminate "news" and make their products available through a variety of means to the general public, as well as news organizations that operate solely on the Internet. Alternative media may be considered to be news-media entities. These examples are not all inclusive.

(1) Factors indicating status as a news media representative include press accreditation, guild membership, a history of continuing publication, business registration, and/or Federal Communication Commission licensing, among others.

(2) For purposes of this definition, news contemplates information that is about current events or that would be of current interest to the public.

(3) A freelance journalist will be treated as a representative of the news media if the person can demonstrate a solid basis for expecting publication of matters related to the requested information through a qualifying news media entity. A publication contract with a qualifying news media entity satisfies this requirement. An individual's past publication record with such organizations is also relevant in making this determination.

§ 70.39 Statutes specifically providing for setting of fees.

This subpart will not apply to fees charged under any statute, other than the FOIA, that specifically requires an agency to set and collect fees for particular types of records.

§ 70.40 Charges assessed for the production of records.

(a) General. Components shall charge for processing requests under the FOIA in accordance with the provisions of this section and with the OMB Guidelines. In order to resolve any fee issues that arise under this section, a component may contact a requester for additional information. Components will ensure that searches, review, and duplication are conducted in the most efficient and least expensive manner. A component ordinarily will collect all applicable fees before sending copies of records to the requester.

(b) There are three types of charges assessed in connection with the production of records in response to a request, specifically, charges for costs associated with:

(1) Searching for or locating responsive records (search costs),

(2) Reproducing such records (reproduction costs), and

(3) Reviewing records to determine whether any materials are exempt (review costs).

(c)(1) There are four types of requesters:

(i) Commercial use requesters,

(ii) Educational and non-commercial scientific institutions,

(iii) Representatives of the news media, and

(iv) All other requesters.

(2) Depending upon the type of requester, as set forth in paragraph (c)(1) of this section, the charges outlined in paragraph (d) of this section may be assessed.

(d) Types of charges that will be assessed for each type of request.

(1) Commercial use request. When a requester makes a commercial use request, search costs, reproduction costs and review costs will be assessed in their entirety.

(2) Educational or non-commercial scientific institution request. When an educational or non-commercial scientific institution makes a request, only reproduction costs will be assessed, excluding charges for the first 100 pages.

(3) Request by representative of news media. When a representative of the news media makes a request, only reproduction costs will be assessed, excluding charges for the first 100 pages.

(4) All other requesters. Requesters making a request which does not fall within paragraphs (d)(1), (2), or (3) of this section will be charged search costs and reproduction costs, except that the first 100 pages of reproduction and the first two hours of search time will be furnished without charge. Where computer searches are involved, the monetary equivalent of two hours of search time by a professional employee will be deducted from the total cost of computer processing time.

(e) Charges for each type of activity.

(1) Search costs.

(i) When a search for records is performed by a clerical employee, a rate of $5.00 per quarter hour will be applicable. When a search is performed by professional or supervisory personnel, a rate of $10.00 per quarter hour will be applicable. Components will charge for time spent searching even if they do not locate any responsive records or they withhold the records located as exempt from disclosure.

(ii) For computer searches of records, requesters will be charged the direct costs of conducting the search, except as provided in paragraph (e)(4) of this section.

(iii) If the search for requested records requires transportation of the searcher to the location of the records or transportation of the records to the searcher, all transportation costs in excess of $5.00 may be added to the search cost.

(2) Reproduction costs. The standard copying charge for records in black and white paper copy is $0.15 per page. This charge includes the operator's time to duplicate the record. When responsive information is provided in a format other than 8½ × 11 or 11 × 14 inch black and white paper copy, such as computer tapes, disks and color copies, the requester may be charged the direct costs of the tape, disk, audio-visual or whatever medium is used to produce the information, as well as the direct cost of reproduction, including operator time. The component may request that if a medium is requested other than paper, the medium will be provided by the requester.

(3) Review costs. Costs associated with the review of records, as defined in § 70.38(e), will be charged for work performed by a clerical employee at a rate of $5.00 per quarter hour when applicable. When professional or supervisory personnel perform work, a rate of $10.00 per quarter hour will be charged, when applicable. Except as noted in this paragraph, charges may only be assessed for review the first time the records are analyzed to determine the applicability of specific exemptions to the particular record or portion of the record. Thus a requester would not be charged for review at the administrative appeal level with regard to the applicability of an exemption already applied at the initial level. When, however, a record has been withheld pursuant to an exemption which is subsequently determined not to apply and is reviewed again at the appellate level to determine the potential applicability of other exemptions, the costs attendant to such additional review will be assessed.

(4) Limitations on charging fees. If a component fails to comply with the time limits in which to respond to a request it shall not assess certain fees except:

(i) If there are unusual circumstances (as that term is defined in Sec. 70.25(c)) and the component has provided timely written notice, the component is permitted ten additional days to respond to the request. After the expiration of the ten additional days, the component is no longer permitted to assess search fees or, in the instances of requests from requesters described in Sec. 70.38 (h) and (i), duplication fees.

(ii) If there are unusual circumstances (as that term is defined in Sec. 70.25(c)), and more than 5,000 pages of documents are deemed to be responsive to the request, the component may continue to charge assessable fees for as long as it takes to process the request, provided that the component has provided timely written notice and discussed with the requester via telephone, email, or written mail (or made at least three good-faith attempts to do so) how the requester could effectively limit the scope of the pending request.

(iii) If a court has determined that exceptional circumstances exist, as defined in the FOIA, 5 U.S.C. 552(a)(6)(C) the agency's failure to comply with any time limits of the FOIA are excused for the length of time provided by the court order.

(5) Mailing cost. Where requests for copies are sent by mail, no postage charge will be made for transmitting by regular mail a single copy of the requested record to the requester, or for mailing additional copies where the total postage cost does not exceed $5.00. However, where the volume of paper copy or method of transmittal requested is such that transmittal charges to the Department are in excess of $5.00, the transmittal costs will be added.

(f) Aggregating requests for purposes of assessing costs.

(1) Where a component reasonably believes that a requester or a group of requesters acting together is attempting to divide a request into a series of requests for the purpose of avoiding fees, the disclosure officer may aggregate those requests and charge accordingly.

(2) Components may presume that multiple requests of this type made within a 30-day period have been submitted in order to avoid fees. Where requests are separated by a longer period, disclosure officers will aggregate them only where a solid basis exists for determining that aggregation is warranted under all of the circumstances involved. Multiple requests involving unrelated matters will not be aggregated.

(g) Interest charges. Components will assess interest on an unpaid bill starting on the 31st day following the date of billing the requester. Interest charges will be assessed at the rate provided in 31 U.S.C. 3717 and will accrue from the date of the billing until payment is received by the component. Components will follow the provisions of the Debt Collection Act of 1982 (Pub. L. 97–365, 96 Stat. 1749), as amended, and its administrative procedures, including the use of consumer reporting agencies, collection agencies, and offset.

(h) Authentication of copies.

(1) Fees. The FOIA does not require certification or attestation under seal of copies of records provided in accordance with its provisions. Pursuant to provisions of the general user-charger statute, 31 U.S.C. 9701 and Subchapter II of title 29 U.S.C., the following charges will be made when, upon request, such services are rendered by the agency in its discretion:

(i) For certification of true copies, $10.00 each certification.

(ii) For attestation under the seal of the Department, $10.00 each attestation under seal.

(2) Authority and form for attestation under seal. Authority is hereby given to any officer or officers of the Department of Labor designated as authentication officer or officers of the Department to sign and issue attestations under the seal of the Department of Labor.

(i) Transcripts. Fees for transcripts of an agency proceeding, as defined in the Administrative Procedure Act, 5 U.S.C. 5521(12) will be assessed in accordance with the provisions of this subpart.

(j) Privacy Act requesters. A request from an individual or on behalf of an individual for a record maintained by that individual's name or other unique identifier which is contained within a component's system of records, will be treated under the fee provisions at 29 CFR 71.6.

§ 70.41 Waiver or reduction of fees.

(a) Requirements for waiver or reduction of fees.

(1) Records responsive to a request will be furnished without charge or at a charge reduced below that established under paragraph (e) of Sec. 70.40, where a Component determines, based on all available information, that the requester has demonstrated that:

(i) Disclosure of the requested information is in the public interest because it is likely to contribute significantly to public understanding of the operations or activities of the government, and

(ii) Disclosure of the information is not primarily in the commercial interest of the requester.

(2) To determine whether the requirement of paragraph (a)(1)(i) of this section is met, components will consider the following factors:

(i) The subject of the request: Whether the subject of the requested records concerns "the operations or activities of the government." The subject of the requested records must concern identifiable operations or activities of the federal government, with a connection that is direct and clear, not remote or attenuated.

(ii) The informative value of the information to be disclosed: Whether the disclosure is "likely to contribute" to an understanding of government operations or activities. The disclosable portions of the requested records must be meaningfully informative about government operations or activities in order to be "likely to contribute" to an increased public understanding of those operations or activities. The disclosure of information that already is in the public domain, in either a duplicative or a substantially identical form, would not be as likely to contribute to such understanding where nothing new would be added to the public's understanding.

(iii) The contribution to an understanding of the subject by the public likely to result from disclosure: Whether disclosure of the requested information will contribute to "public understanding." The disclosure must contribute to the understanding of a reasonably broad audience of persons interested in the subject, as opposed to the individual understanding of the requester. A requester's expertise in the subject area and ability and intention to effectively convey information to the public will be considered. It will be presumed that a representative of the news media will satisfy this consideration.

(iv) The significance of the contribution to public understanding: Whether the disclosure is likely to contribute "significantly" to the public understanding of government operations or activities. The public's understanding of the subject in question must be enhanced by the disclosure to a significant extent.

(3) To determine whether the requirement of paragraph (a)(1)(ii) of this section is met, components will consider the following factors:

(i) The existence and magnitude of a commercial interest: Whether the requester has a commercial interest that would be furthered by the requested disclosure. The component will consider any commercial interest of the requester (with reference to the definition of "commercial use request" in Sec. 70.38(f)), or of any person on whose behalf the requester may be acting, that would be furthered by the requested disclosure. Requesters will be given an opportunity in the administrative process to provide explanatory information regarding this consideration.

(ii) The primary interest in disclosure: Whether any identified commercial interest of the requester is sufficiently large, in comparison with the public interest in disclosure, that disclosure is "primarily in the commercial interest of the requester." A fee waiver or reduction is justified where the public interest standard is satisfied and that public interest is greater in magnitude than that of any identified commercial interest in disclosure. The component ordinarily will presume that where a news media requester has satisfied the public interest standard, the public interest will be the interest primarily served by disclosure to that requester. Disclosure to data brokers or others who merely compile and market government information for direct economic return will not be presumed to primarily serve the public interest.

(4) Where only some of the records to be released satisfy the requirements for a waiver of fees, a waiver will be granted only for those records.

(5) Requests for the waiver or reduction of fees should address the factors listed in paragraph (a) of this section, insofar as they apply to each request.

(b) Submission. Requests for a waiver or reduction of fees should be made when the request is first submitted to the component and should address the criteria referenced above. A requester may submit a fee waiver request at a later time so long as the underlying record request is pending or on administrative appeal. When a requester who has committed to pay fees subsequently asks for a waiver of those fees and that waiver is denied, the requester will be required to pay any costs incurred up to the date the fee waiver request was received.

(c) Appeal rights. Requesters dissatisfied with treatment of fee waiver or reduction requests may follow the procedures for appeal under Sections 70.22 and 70.23.

§ 70.42 Consent to Pay Fees.

(a) The Department will not assess or collect fees where the fee to be assessed, after deducting any free pages and/or search time, is less than $25.00. When making a request, a requester may specify a willingness to pay up to a certain amount, *e.g.*, $50.00 or $200.

(b) No request will be processed if a component reasonably believes that the fees are likely to exceed the amount to which the requester has originally consented, absent supplemental written consent by the requester to proceed after being notified of this determination.

(c) When a component determines or estimates that the fees to be assessed in accordance with this section will exceed $25.00, the component shall notify the requester of the actual or estimated amount of the fees, including a breakdown of the fees for search, review or duplication, unless the requester has indicated a willingness to pay fees as high as those anticipated. If only a portion of the fee can be estimated readily, the component must advise the requester accordingly. Such notice may invite the requester to reformulate the request to satisfy his or her needs at a lower cost.

(d) Components must make available their FOIA contact to assist any requester in reformulating a request to meet the requester's needs at a lower cost.

§ 70.43 Payment of fees.

(a) De minimis costs. As noted in Sec. 70.42(a), the Department has determined it will not assess or collect fees below $25.00. In these cases, the cost of collecting and processing a fee equals or exceeds the amount of the fee which would otherwise be assessed. The Department will assess fees where the costs to be assessed, after deduction of any free pages and/or search time, is $25.00 or higher.

(b) How payment will be made. Requesters will pay fees assessed by check or money order made payable to the Treasury of the United States, and sent to the component that is processing the request.

(c) Advance payments and billing.

(1) Prior to beginning to process a request, the component will make a preliminary assessment of the amount that can properly be charged to the requester for search and review time and copying costs. Where a component determines or estimates that a total fee to be charged under this section will be more than $250.00, the component will require the requester to make an advance payment of an amount up to the entire anticipated fee before beginning to process the request. The component may waive the advance payment where the component receives a satisfactory assurance of full payment from a requester who has a history of prompt payment of an amount similar to the one anticipated by the request.

(2) Where a requester has previously failed to pay a properly charged FOIA fee to any component of the Department of Labor within 30 days of the date of billing, a component will require the requester to pay the full amount due, plus any applicable interest as provided in Sec. 70.40(f) and to make an advance payment of the full amount of any anticipated fee, before the component begins to process a new request or appeal or continues to process a pending request or appeal from that requester.

(3) For a request other than those described in paragraphs (c)(1) and (2) of this section, a component will not require the requester to make an advance payment before beginning to process a request. Payment owed for work already completed on a request pursuant to consent of the requester is not an advance payment and a component may require the requester to make a payment for such work prior to releasing any records to the requester.

(d) Time limits to respond extended when advance payments are requested. When a component has requested an advance payment of fees in accordance with paragraph (c) of this section, the time limits prescribed in Sec. 70.25 will only begin to run after the component has received the advance payment.

§ 70.44 Other rights and services.

Nothing in this subpart will be construed to entitle any person, as of right, to any service or to the disclosure of any records to which such person is not entitled under the FOIA.

§ 70.45–70.52 [Reserved]

Subpart D—Public Records and Filings

§ 70.53 Office of Labor-Management Standards.

(a) The following documents in the custody of the Office of Labor-Management Standards are public information available for inspection and/or purchase of copies in accordance with paragraphs (b) and (c) of this section.

(1) Data and information contained in any report or other document filed pursuant to sections 201, 202, 203, 211, 301 of the Labor-Management Reporting and Disclosure Act of 1959 (73 Stat. 524–28, 530, 79 Stat. 888, 73 Stat. 530, 29 U.S.C. 431–433, 441, 461).

(2) Data and information contained in any report or other document filed pursuant to the reporting requirements of 29 CFR part 458, which are the regulations implementing the standards of conduct provisions of the Civil Service Reform Act of 1978, 5 U.S.C. 7120, and the Foreign Service Act of 1980, 22 U.S.C. 4117. The reporting requirements are found in 29 CFR 458.3.

(3) Data and information contained in any report or other document filed pursuant to the Congressional Accountability Act of 1995, 2 U.S.C. 1351, 109 Stat. 19.

(b) The documents listed in paragraph (a) of this section are available from: U.S. Department of Labor, Office of Labor-Management Standards, Public Disclosure Room, N–5608, 200 Constitution Avenue NW., Washington, DC 20210. Reports filed pursuant to section 201 of the Labor-Management Reporting and Disclosure Act of 1959 and pursuant to 29 CFR 458.3 implementing the Civil Service Reform Act of 1978 and the Foreign Service Act of 1980 for the year 2000 and thereafter are also available at *http://www.union-reports.dol.gov.*

(c) Pursuant to 29 U.S.C. 435(c) which provides that the Secretary will by regulation provide for the furnishing of copies of the documents listed in paragraph (a) of this section, upon payment of a charge based upon the cost of the service, these documents are available at a cost of $ .15 per page for record copies furnished. Authentication of copies is available in accordance with the fee schedule established in Sec. 70.40. In accordance with 5 U.S.C. 552(a)(4)(A)(vi), the provisions for fees, fee waivers and fee reductions in subpart C of this part do not supersede these charges for these documents.

(d) Upon request of the Governor of a State for copies of any reports or documents filed pursuant to sections 201, 202, 203, or 211 of the Labor-Management Reporting and Disclosure Act of 1959 (73 Stat. 524–528, 79 Stat. 888; 29 U.S.C. 431–433, 441), or for information contained therein, which have been filed by any person whose principal place of business or headquarters is in such State, the Office of Labor-Management Standards will:

(1) Make available without payment of a charge to the State agency designated by law or by such Governor, such requested copies of information and data, or

(2) Require the person who filed such reports and documents to furnish such copies or information and data directly to the State agency thus designated.

§ 70.54 Employee Benefits Security Administration.

(a) The annual financial reports (Form 5500) and attachments/schedules as filed by employee benefit plans under the Employee Retirement Income Security Act (ERISA) are in the custody of the Employee Benefits Security Administration (EBSA) at the address indicated in paragraph (b) of this section, and the right to inspect and copy such reports, as authorized under ERISA, at the fees set forth in this part, may be exercised at such office.

(b) The mailing address for the documents described in this section is: U.S. Department of Labor, Employee Benefits Security Administration, Public Documents Room, 200 Constitution Avenue NW., Washington, DC 20210.

Appendix A to Part 70—FOIA Components

The following list identifies the individual agency components of the Department of Labor for the purposes of the FOIA. Each component is responsible for making records in its custody available for inspection and copying, in accordance with the provisions of the FOIA and this part. Unless otherwise specified, the mailing addresses for the following national office components are listed below. Updated contact information for national and regional offices can be found on the DOL Web site at *http://www.dol.gov/dol/foia.*

U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

1. Office of the Secretary (OSEC)
2. Office of the Solicitor (SOL)
3. Office of Administrative Law Judges (ALJ), 800 K Street NW., Suite N–400, Washington, DC 20001–8002
4. Office of the Assistant Secretary for Administration and Management (OASAM),
5. Office of the Assistant Secretary for Policy (OASP).
6. Office of the Chief Financial Officer (OCFO).
7. Office of Congressional and Intergovernmental Affairs (OCIA).
8. Office of Disability Employment Policy (ODEP).
9. Office of Federal Contract Compliance Programs (OFCCP).
10. Office of the Inspector General (OIG).
11. Office of Labor Management Standards (OLMS).
12. Office of Public Affairs (OPA).
13. Office of Workers' Compensation Programs (OWCP).
14. Bureau of International Labor Affairs (ILAB).
15. Bureau of Labor Statistics (BLS), Postal Square Building, Room 4040, 2 Massachusetts Avenue NE., Washington, DC 20212–0001.
16. Employment and Training Administration (ETA).

Job Corps (part of ETA).

17. Mine Safety and Health Administration (MSHA), 201 12th Street, South, Arlington, Virginia 22202.
18. Occupational Safety and Health Administration (OSHA).
19. Employee Benefits Security Administration (EBSA).
20. Veterans' Employment and Training Service (VETS).
21. Employees' Compensation Appeals Board (ECAB).
22. Administrative Review Board (ARB).
23. Benefits Review Board (BRB).
24. Wage and Hour Division (WHD).
25. Women's Bureau (WB).

Signed at Washington, DC, on August 1, 2016.

Thomas E. Perez,

Secretary of Labor.

[FR Doc. 2016–18594 Filed 8–16–16; 8:45 am]

BILLING CODE P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[EPA–R04–OAR–2016–0312; FRL–9950–81–Region 4]

Air Plan Approval; Kentucky; Removal of Stage II Gasoline Vapor Recovery Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The Environmental Protection Agency (EPA) is proposing to approve changes to the Kentucky State Implementation Plan (SIP) submitted by the Commonwealth of Kentucky through its Energy and Environment Cabinet (EEC) on May 3, 2016. This SIP revision seeks to remove Stage II vapor control requirements for new and upgraded gasoline dispensing facilities in the State and allow for the decommissioning of existing Stage II equipment in Boone, Campbell and Kenton Counties in Kentucky. EPA has preliminarily determined that Kentucky's May 3, 2016, SIP revision is approvable because it is consistent with the Clean Air Act (CAA or Act).

DATES: Written comments must be received on or before September 16, 2016.

ADDRESSES: Submit your comments, identified by Docket ID No. EPA–R04–OAR–2016–0312 at *http://www.regulations.gov.* Follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Kelly Sheckler, Air Regulatory

Management Section, Air Planning and Implementation Branch, Air, Pesticides and Toxics Management Division, U.S. Environmental Protection Agency, Region 4, 61 Forsyth Street SW., Atlanta, Georgia 30303–8960. Ms. Sheckler's phone number is (404) 562–9222. She can also be reached via electronic mail at *sheckler.kelly@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background for Federal Stage II Requirements

Stage I vapor recovery is a type of emission control system that captures gasoline vapors that are released when gasoline is delivered to a storage tank. The vapors are returned to the tank truck as the storage tank is being filled with fuel, rather than released to the ambient air. Stage II and onboard refueling vapor recovery (ORVR) are two types of emission control systems that capture fuel vapors from vehicle gas tanks during refueling. Stage II systems are specifically installed at gasoline dispensing facilities and capture the refueling fuel vapors at the gasoline pump nozzle. The system carries the vapors back to the underground storage tank at the gasoline dispensing facility to prevent the vapors from escaping to the atmosphere. ORVR systems are carbon canisters installed directly on automobiles to capture the fuel vapors evacuated from the gasoline tank before they reach the nozzle. The fuel vapors captured in the carbon canisters are then combusted in the engine when the automobile is in operation.

Under section 182(b)(3) of the CAA, each state was required to submit a SIP revision to implement Stage II for all ozone nonattainment areas classified as moderate, serious, severe, or extreme, primarily for the control of volatile organic compounds (VOC)—a precursor to ozone formation.[1] However, section 202(a)(6) of the CAA states that the section 182(b)(3) Stage II requirements for moderate ozone nonattainment areas shall not apply after the promulgation of ORVR standards.[2] ORVR standards were promulgated by EPA on April 6, 1994. *See* 59 FR 16262 and 40 CFR parts 86, 88 and 600. As a result, the CAA no longer requires moderate areas to impose Stage II controls under section 182(b)(3), and such areas were able to submit SIP revisions, in compliance with section 110(l) of the CAA, to remove Stage II requirements from their SIPs. EPA's policy memoranda related to ORVR, dated March 9, 1993, and June 23, 1993, provide further guidance on removing Stage II requirements from certain areas. The policy memorandum dated March 9, 1993, states that ''[w]hen onboard rules are promulgated, a State may withdraw its Stage II rules for moderate areas from the SIP (or from consideration as a SIP revision) consistent with its obligations under sections 182(b)(3) and 202(a)(6), so long as withdrawal will not interfere with any other applicable requirement of the Act.'' [3]

CAA section 202(a)(6) also provides discretionary authority to the EPA Administrator to, by rule, revise or waive the section 182(b)(3) Stage II requirement for serious, severe, and extreme ozone nonattainment areas after the Administrator determines that ORVR is in widespread use throughout the motor vehicle fleet. On May 16, 2012, in a rulemaking entitled ''Air Quality: Widespread Use for Onboard Refueling Vapor Recovery and Stage II Waiver,'' EPA determined that ORVR technology is in widespread use throughout the motor vehicle fleet for purposes of controlling motor vehicle refueling emissions. *See* 77 FR 28772. By that action, EPA waived the requirement for states to implement Stage II gasoline vapor recovery systems at gasoline dispensing facilities in nonattainment areas classified as serious and above for the ozone NAAQS. Effective May 16, 2012, states implementing mandatory Stage II programs under section 182(b)(3) of the CAA were allowed to submit SIP revisions to remove this program. *See* 40 CFR 51.126(b).[4] On April 7, 2012, EPA released the guidance entitled ''Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures'' for states to consider in preparing their SIP revisions to remove existing Stage II programs from state implementation plans.[5]

II. Kentucky's Stage II Requirements for the Northern Kentucky Area

On November 6, 1991, EPA designated and classified Boone, Campbell and Kenton Counties in Kentucky (hereinafter referred to as the ''Northern Kentucky Area'' or ''Area'') as part of the seven-county area in and around the Cincinnati-Hamilton, OH-KY, area as a moderate nonattainment area for the 1-hour ozone NAAQS.[6] *See* 56 FR 56694, 56764. As mentioned above, the ''moderate'' classification triggered various statutory requirements for this Area, including the requirement pursuant to section 182(b)(3) of the CAA for the Area to require all owners and operators of gasoline dispensing systems to install and operate a system for gasoline vapor recovery of emissions from the fueling of motor vehicles known as ''Stage II.'' [7]

On February 3, 1998, the Commonwealth of Kentucky submitted a SIP revision to address the Stage II requirements for the Northern Kentucky Area. EPA approved that SIP revision, containing Kentucky regulation 401 KAR 59:174—*Stage II controls at gasoline dispensing facilities,* in a notice published on February 8, 1999. 63 FR 67586. Northern Kentucky's Stage II rule, as currently incorporated into the SIP, requires that Stage II systems be tested and certified to meet a 95 percent emission reduction efficiency by using a system approved by the California Air Resources Board (CARB). The rule requires sources to verify proper installation and function of Stage II equipment through use of a liquid blockage test and a leak test prior to system operation and every five years or upon major modification of a facility (*i.e.,* 75 percent or more equipment change). The Commonwealth also established an inspection program consistent with that described in EPA's Stage II guidance and has established procedures for enforcing violations of the Stage II requirements.

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[1] Section 182(b)(3) states that each State in which all or part of an ozone nonattainment area classified as moderate or above shall, with respect to that area, submit a SIP revision requiring owners or operators of gasoline dispensing systems to install and operate vapor recovery equipment at their facilities. Specifically, the CAA specifies that the Stage II requirements must apply to any facility that dispenses more than 10,000 gallons of gasoline per month or, in the case of an independent small business marketer (ISBM), as defined in section 324 of the CAA, any facility that dispenses more than 50,000 gallons of gasoline per month. Additionally, the CAA specifies the deadlines by which certain facilities must comply with the Stage II requirements. For facilities that are not owned or operated by an ISBM, these deadlines, calculated from the time of State adoption of the Stage II requirements, are: (1) 6 months for facilities for which construction began after November 15, 1990, (2) 1 year for facilities that dispense greater than 100,000 gallons of gasoline per month, and (3) by November 15, 1994, for all other facilities. For ISBMs, section 324(a) of the CAA provides the following three-year phase-in period: (1) 33 percent of the facilities owned by an ISBM by the end of the first year after the regulations take effect; (2) 66 percent of such facilities by the end of the second year; and (3) 100 percent of such facilities after the third year.

[2] ORVR is a system employed on gasoline-powered highway motor vehicles to capture gasoline vapors displaced from a vehicle fuel tank during refueling events. These systems are required under section 202(a)(6) of the CAA and implementation of these requirements began in the 1998 model year. Currently they are used on all gasoline-powered passenger cars, light trucks and complete heavy trucks of less than 14,000 pounds GVWR. ORVR systems typically employ a liquid file neck seal to block vapor escape to the atmosphere and otherwise share many components with the vehicles' evaporative emission control system including the onboard diagnostic system sensors.

[3] Memorandum from John S. Seitz, Director, Office of Air Quality Planning and Standards, to EPA Regional Air Directors, *Impact of the Recent Onboard Decision on Stage II Requirements in Moderate Areas* (March 9, 1993), available at: *http://www.epa.gov/ttn/naaqs/aqmguide/collection/cp2/19930309_seitz_onboard_impact_stage2_.pdf.*

[4] As noted above, EPA found, pursuant to CAA section 202(a)(6), that ORVR systems are in widespread use in the motor vehicle fleet and waived the CAA section 182(b)(3) Stage II vapor recovery requirement for serious and higher ozone nonattainment areas on May 16, 2012. Thus, in its implementation rule for the 2008 ozone NAAQS, EPA removed the section 182(b)(3) Stage II requirement from the list of applicable requirements in 40 CFR 51.1100(o). See 80 FR 12264 for additional information.

[5] This guidance document is available at: *http://www.epa.gov/groundlevelozone/pdfs/20120807guidance.pdf.*

[6] The other counties in this nonattainment area were Butler, Clermont, Hamilton and Warren Counties in Ohio. *See* 56 FR 56813.

[7] As discussed above, Stage II is a system designed to capture displaced vapors that emerge from inside a vehicle's fuel tank when gasoline is dispensed into the tank. There are two basic types of Stage II systems, the balance type and the vacuum assist type.

On December 13, 1999, Kentucky submitted to EPA a request to redesignate the Northern Kentucky Area to attainment for the 1-hour ozone standard and an associated maintenance plan. The maintenance plan, as required under section 175A of the CAA, showed that nitrogen oxides and VOC emissions in the Area would remain below the 1996 "attainment year" levels through the greater than ten-year period from 1996–2010. In making these projections, Kentucky factored in the emissions benefit of the Area's Stage II program, thereby maintaining this program as an active part of its 1-hour ozone SIP. Originally, the redesignation request and maintenance plan were approved by EPA, effective July 5, 2000. *See* 65 FR 37879. However, the United States Court of Appeals for the Sixth Circuit vacated EPA's approval of this redesignation request and maintenance plan and remanded it back to EPA after the Court concluded that EPA erred in one respect pertaining only to the Ohio portion of the Area. On July 31, 2002, EPA reinstated the approval of the redesignation request and maintenance plan for Kentucky. *See* 67 FR 49600.

Subsequently, Boone, Campbell and Kenton Counties in Kentucky (or portions thereof) were designated nonattainment as a part of a larger tri-state nonattainment area which included Kentucky, Ohio and Indiana counties in and around the Cincinnati area for both the 1997 8-hour ozone and 2008 8-hour ozone NAAQS. On August 5, 2010, the Area (*i.e.,* the Kentucky portion of the tri-state Cincinnati-Hamilton Area) was redesignated to attainment of the 1997 8-hour ozone NAAQS. *See* 75 FR 47218. The tri-state Cincinnati-Hamilton Area is attaining the 2008 8-hour ozone NAAQS, and the Commonwealth is in the process of submitting a redesignation request and maintenance plan for the 2008 8-hour ozone NAAQS.

III. Analysis of the Commonwealth's Submittal

On May 3, 2016, the Commonwealth of Kentucky submitted a SIP revision to EPA seeking modifications of the Stage II requirements in the Northern Kentucky Area. Specifically, it seeks the removal of the Stage II requirements in Kentucky regulation 401 KAR 59:174—*Stage II Controls at gasoline dispensing facilities.* These modifications would remove Stage II vapor control requirements for new and upgraded gasoline dispensing facilities in the State and allow for the decommissioning of existing Stage II equipment.

EPA's primary consideration for determining the approvability of the Commonwealth of Kentucky's request is whether this requested action complies with section 110(l) of the CAA.[8] Section 110(l) requires that a revision to the SIP not interfere with any applicable requirement concerning attainment and reasonable further progress (as defined in section 171), or any other applicable requirement of the Act. EPA evaluates each section 110(l) noninterference demonstration on a case-by-case basis, considering the circumstances of each SIP revision. EPA interprets 110(l) as applying to all NAAQS that are in effect, including those that have been promulgated but for which the EPA has not yet made designations. The degree of analysis focused on any particular NAAQS in a noninterference demonstration varies depending on the nature of the emissions associated with the proposed SIP revision. EPA's analysis of Kentucky's May 3, 2016, SIP revision pursuant to section 110(l) is provided below.

In its May 3, 2016, SIP revision, Kentucky used EPA's guidance entitled "Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures" to conduct a series of calculations to determine the potential impact on air quality of removing the Stage II program.[9] Kentucky's analysis focused on VOC emissions because, as mentioned above, Stage II requirements affect VOC emissions and because VOC are a precursor for ozone formation.[10] The results of Kentucky's analysis are provided in the table below.

TABLE 1—VOC EMISSIONS DIFFERENCE BETWEEN STAGE II VRS IN PLACE AND REMOVED

Year	VOC emissions (tons per day)
2011	N/A
2014	−0.21
2017	−0.15
2020	−0.10

Table 1 shows that the removal of Stage II vapor recovery systems in the Northern Kentucky Area starting in 2014 would have resulted and will result in a VOC emission decrease. If instead Stage II requirements are kept in place, VOC emissions will decrease by less, and it will less beneficial to air quality in Northern Kentucky to keep Stage II systems in operation.[11]

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[8] CAA section 193 is not relevant because Kentucky's Stage II rule was not included in the SIP before the 1990 CAA amendments.

[9] EPA, Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures, EPA–457/B–12–001 (Aug. 7, 2012), available at *https://www.epa.gov/ozone-pollution/ozone-stage-two-vapor-recovery-rule-and-guidance.* This guidance document notes that "the potential emission control losses from removing Stage II VRS are transitional and relatively small. ORVR-equipped vehicles will continue to phase in to the fleet over the coming years and will exceed 80 percent of all highway gasoline vehicles and 85 percent of all gasoline dispensed during 2015. As the number of these ORVR-equipped vehicles increase, the control attributed to Stage II VRS will decrease even further, and the potential foregone Stage II VOC emission reductions are generally expected to be no more than one percent of the VOC inventory in the area."

[10] Two counties in Kentucky are currently designated nonattainment for the 1997 Annual fine particulate matter ($PM_{2.5}$) standard: Bullitt and Jefferson. While VOC is one of the precursors for particulate matter (NAAQS) formation, studies have indicated that, in the southeast, emissions of direct $PM_{2.5}$ and the precursor sulfur oxides are more significant to ambient summertime $PM_{2.5}$ concentrations than emissions of nitrogen oxides and anthropogenic VOC. *See, e.g., Quantifying the sources of ozone, fine particulate matter, and regional haze in the Southeastern United States,* Journal of Environmental Management (2009), available at: *http://www.sciencedirect.com/science/article/pii/S0301479709001893.*

[11] The emissions-reduction disbenefit associated with continued implementation of Stage II requirements is due to the incompatibility of some Stage II and ORVR systems. Compatibility problems can result in an increase in emissions from the underground storage tank (UST) vent pipe and other system fugitive emissions related to the refueling of ORVR vehicles with some types of vacuum assist-type Stage II systems. This occurs during refueling an ORVR vehicle when the vacuum assist system draws fresh air into the UST rather than an air vapor mixture from the vehicle fuel tank. Vapor flow from the vehicle fuel tank is blocked by the liquid seal in the fill pipe which forms at a level deeper in the fill pipe than can be reached by the end of the nozzle spout. The fresh air drawn into the UST enhances gasoline evaporation in the UST which increases pressure in

The affected sources covered by Kentucky's Stage II vapor recovery requirements are sources of VOC. Other criteria pollutants (carbon monoxide, sulfur dioxide, nitrogen dioxide, particulate matter, and lead) are not emitted by gasoline dispensing facilities and will not be affected by the removal of Stage II controls.

The proposed revisions to 401 KAR 59:174 include that gasoline dispensing facilities located in Boone, Campbell and Kenton Counties shall decommission and remove the systems no later than December 31, 2018. Kentucky noted in its submission that the decommissioning procedures in the revised version of 401 KAR 59:174 follow Petroleum Equipment Institute (PEI) guidance, "Recommended Practices for Installation and Testing of Vapor Recovery Systems at Vehicle Refueling Sites," PEI/RP300–09.

EPA is proposing to determine that Kentucky's technical analysis is consistent with EPA's guidance on removing Stage II requirements from a SIP, including as it relates to the decommissioning and phasing out of the Stage II requirements for the Northern Kentucky Area. EPA is also making the preliminary determination that Kentucky's SIP revision is consistent with the CAA and with EPA's regulations related to removal of Stage II requirements from the SIP and that these changes will not interfere with any applicable requirement concerning attainment or any other applicable requirement of the CAA, and therefore satisfy section 110(l).

IV. Incorporation by Reference

In this rule, EPA is proposing to include in a final EPA rule regulatory text that includes incorporation by reference. In accordance with requirements of 1 CFR 51.5, EPA is proposing to incorporate by reference Kentucky Regulation 401 KAR 59:174—*Stage II controls at gasoline dispensing facilities,* effective March 4, 2016. EPA has made, and will continue to make, these materials generally available through *www.regulations.gov* and/or at the EPA Region 4 office (please contact the person identified in the **FOR FURTHER INFORMATION CONTACT** section of this preamble for more information).

V. Proposed Action

EPA is proposing to approve the Commonwealth of Kentucky's May 3, 2016, SIP revision that changes Kentucky's Stage II rule, 401 KAR 59:174, to allow for the removal of the Stage II requirement and the orderly decommissioning of Stage II equipment. EPA is proposing this approval because the Agency has made the preliminary determination that the Commonwealth of Kentucky's May 3, 2016, SIP revision related to the Commonwealth's Stage II rule is consistent with the CAA and with EPA's regulations and guidance.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a "significant regulatory action" subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Authority: 42 U.S.C. 7401 *et seq.*

Dated: August 8, 2016.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2016–19538 Filed 8–16–16; 8:45 am]

BILLING CODE 6560–50–P

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the UST. Unless it is lost as a fugitive emission, any tank pressure in excess of the rating of the pressure/vacuum valve is vented to the atmosphere over the course of a day. *See* EPA, Guidance on Removing Stage II Gasoline Vapor Control Programs from State Implementation Plans and Assessing Comparable Measures, EPA–457/B–12–001 (Aug. 7, 2012), available at: *https://www.epa.gov/ozone-pollution/ozone-stage-two-vapor-recovery-rule-and-guidance.* Thus, as ORVR technology is phased in, the amount of emission control that is gained through Stage II systems decreases.

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 1801, 1815, and 1852

RIN 2700–AE35

Remove NASA FAR Supplement Clause, Engineering Change Proposals (2016–N030)

AGENCY: National Aeronautics and Space Administration.

ACTION: Proposed rule.

SUMMARY: National Aeronautics and Space Administration (NASA) is proposing to amend the NASA FAR Supplement (NFS) to remove NFS clause 1852.243–70, Engineering Change Proposals (ECPs) basic clause with its Alternate I & II and associated information collection from the NFS.

DATES: Comments on the proposed rule should be submitted in writing to the address shown below on or before October 17, 2016 to be considered in formulation of the final rule.

ADDRESSES: Submit comments identified by NFS Case 2016–N030, using any of the following methods:

○ *Regulations.gov: http://www.regulations.gov.* Submit comments via the Federal eRulemaking portal by entering "NFS Case 2016–N030" under the heading "Enter keyword or ID" and selecting "Search." Select the link "Submit a Comment" that corresponds with "NFS Case 2016–N030." Follow the instructions provided at the "Submit a Comment" screen. Please include your name, company name (if any), and "NFS Case 2016–N030" on your attached document.

○ *Email: andrew.orourke@nasa.gov.* Include NFS Case 2016–N030 in the subject line of the message.

○ *Fax:* (202) 358–3082.

○ *Mail:* National Aeronautics and Space Administration, Headquarters, Office of Procurement, Contract and Grant Policy Division, Attn: Andrew O'Rourke, LP–011, Suite 5L32, 300 E. Street SW., Washington, DC 20546–0001.

FOR FURTHER INFORMATION CONTACT: Andrew O'Rourke, NASA, Office of Procurement, Contract and Grant Policy Division, Suite 5L32, 300 E. Street SW., Washington, DC 20456–0001. Telephone (202) 358–4560; facsimile (202) 358–3082; email: *andrew.orourke@nasa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

NASA FAR Supplement clause 1852.243–70, Engineering Change Proposals, requires NASA contractors and vendors to submit contract change proposal information. The Office of Management and Budget (OMB) has approved the collection of this information via OMB Control Number 2700–054 that expires on September 30, 2017. In processing the request for renewal of this information collection under OMB Control Number 2700–054 and as part of NASA's continuing retrospective review of existing regulations to reduce unnecessary, outdated and/or burdensome requirements, NASA Office of Procurement (OP) surveyed its procurement offices to ascertain whether or not NFS clause 1852.243–70, Engineering Change Proposals, was necessary. The results of the review indicated that NFS clause 1852.243–70 was no longer utilized in procurements. Instead, the FAR Changes clauses (FAR 52.243–1 through 52.243–5) were being utilized to process engineering change proposals in lieu of this NFS clause. Thus, NASA is proposing to delete NFS clause 1852.243–70, Engineering Change Proposals, with its Alternate I & II and the corresponding information collection under OMB Control Number 2700–054.

II. Discussion

NASA is proposing the following revisions to eliminate unnecessary NFS requirements:

- Delete NFS segment 1843 and OMB Control Number 2700–054 from 1801.106–1.
- Remove the prescription at NFS 1843.205–70(a).
- Delete NFS clause 1852.243–70, Engineering Change Proposals.

III. Executive Orders 12866 and 13563

Executive Orders (E.O.s) 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health, and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This is not a significant regulatory action and, therefore, was not subject to review under section 6(b) of E.O. 12866, Regulatory Planning and Review, dated September 30, 1993. This proposed rule is not a major rule under 5 U.S.C. 804.

IV. Regulatory Flexibility Act

NASA does not expect this proposed rule to have a significant economic impact on a substantial number of small entities within the meaning of the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.,* because we are removing a NFS clause and its associated information collection requirements for contractors. By removing this clause, the information collection requirement on contractors will be eliminated, thus providing all entities, both large and small, with a positive benefit. However, an initial regulatory flexibility analysis has been performed and is summarized as follows:

In preparing the request for renewal of this information collection under OMB Control Number 2700–054 and as part of NASA's continuing retrospective review of existing regulations to reduce unnecessary, outdated and/or burdensome requirements, NASA Office of Procurement its procurement offices to ascertain whether or not NFS clause 1852.243–70, Engineering Change Proposals, was necessary. The results of the review indicated that NFS clause 1852.243–70 was no longer utilized in procurements. Instead, the FAR changes clauses were being utilized to process engineering change proposals in lieu of this NFS clause. Thus, NASA is proposing to delete NFS clause 1852.243–70, Engineering Change Proposals, with its Alternate I & II and the corresponding information collection under OMB Control Number 2700–054. This proposed rule does not include any new reporting, recordkeeping, or other compliance requirements for small businesses. The proposed rule does not duplicate, overlap, or conflict with any other Federal rules. No alternative approaches were considered.

NASA invites comments from small business concerns and other interested parties on the expected impact of this rule on small entities.

NASA will also consider comments from small entities concerning the existing regulations in subparts affected by this rule in accordance with 5 U.S.C. 610. Interested parties must submit such comments separately and should cite 5 U.S.C. 610 (NFS case 2016–N030) in correspondence.

C. Paperwork Reduction Act

The rule contains information collection requirements that require the approval of the OMB under the Paperwork Reduction Act (44 U.S.C chapter 35); however, the proposed changes to the NFS would remove the information collection requirements previously approved under OMB Control Number 2700–0054, entitled NFS 1843 Contract Modifications for Engineering Change Proposals (ECP).

List of Subjects in 48 CFR Parts 1801, 1843, and 1852

Government procurement.

Manuel Quinones,

NASA FAR Supplement Manager.

Accordingly, 48 CFR parts 1801, 1843, and 1852 are proposed to be amended as follows:

■ 1. The authority citation for parts 1801, 1843 and 1852 continues to read as follows:

Authority: 51 U.S.C. 20113(a) and 48 CFR chapter 1.

PART 1801—FEDERAL ACQUISITION REGULATIONS SYSTEM

■ 2. Revise Section 1801.106 to read as follows:

1801.106 OMB approval under the Paperwork Reduction Act.

The following OMB control numbers apply:

NFS segment	OMB Control No.
1823	2700–0089
1827	2700–0052
1852.223–70	2700–0160
NF 533	2700–0003
NF 1018	2700–0017

PART 1843—CONTRACT MODIFICATIONS

■ 3. Revise Section 1843.205–70 to read as follows:

1843.205–70 NASA contract clauses.

The contracting officer may insert a clause substantially as stated at 1852.243–72, Equitable Adjustments, in solicitations and contracts for—

(a) Dismantling, demolishing, or removing improvements; or

(b) Construction, when the contract amount is expected to exceed the simplified acquisition threshold and a fixed-price contract is contemplated.

PART 1852—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

1852.243–70 [Removed and reserved]

■ 4. Section 1852.243–70 is removed and reserved.

1852.243–72 [Amended]

■ 5. Amend section 1852.243–72 by removing ''1843.205–70(b)'' and adding ''1843.205–70'' in its place in the introductory text.

[FR Doc. 2016–19566 Filed 8–16–16; 8:45 am]

BILLING CODE 7510–13–P

Notices

Federal Register
Vol. 81, No. 159
Wednesday, August 17, 2016

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Forest Service

Revision of the Land Management Plan for Francis Marion National Forest

AGENCY: Forest Service, USDA.

ACTION: Notice of the opportunity to object to the Revised Land Management Plan for the Francis Marion National Forest prior to approval

SUMMARY: The Francis Marion National Forest, located in South Carolina, has prepared an environmental impact statement, a revised land management plan and a draft record of decision. This notice is to inform the public that a 60-day period is being initiated where individuals or entities with specific concerns on the Francis Marion's Revised Land Management Plan and its associated Final Environmental Impact Statement may file an objection for a Forest Service review prior to the approval of the Revised Land Management Plan.

DATES: The Francis Marion's Revised Land Management Plan, Final Enviromental Impact Statement, Draft Record of Decision, and other supporting information, will be available for review at *http://www.fs.usda.gov/detail/scnfs/landmanagement/planning/?cid=stelprdb5393142* starting August 19, 2016.

A legal notice of the initiation of the 60-day objection period is also being published in the Francis Marion and Sumter National Forests newspaper of record, which is *The State.* The date of the publication of the legal notice in *The State* will determine the actual date of initiation of the 60-day objection period. A copy of the legal notice that is published in *The State* will be posted on the Web site described above.

ADDRESSES: Copies of the Revised Land Mangement Plan for the Francis Marion National Forest, Final Environment Impact Statement, and Draft Record of Decision can be obtained online at: *http://www.fs.usda.gov/detail/scnfs/landmanagement/planning/?cid=stelprdb5393142* or at the following offices:

- Supervisor's Office, 4931 Broad River Road, Columbia, SC 29212 (Telephone: 803–561–4000)
- Francis Marion District Office, 2967 Steed Creek Road, Huger, SC 29450 (Telephone: 843–336–3248)

Objections must be submitted to the Reviewing Officer Tony Tooke, Regional Forester, at USDA-Forest Service, ATTN: Objection Reviewing Officer, 1720 Peachtree Street, Atlanta, GA 30309 (Telephone: 404–347–4177; Fax: 404–347–4821). Or objections may be submitted electronically at *objections-southern-regional-office@fs.fed.us*

Note that the office hours for submitting a hand-delivered objection are 8:00 a.m. to 4:30 p.m. Monday through Friday, excluding Federal holidays. Electronic objections must be submitted in a commonly used format such as an email message, plain text (.txt), rich text format (.rtf) or Microsoft Word® (.doc or .docx).

FOR FURTHER INFORMATION CONTACT: Mary Morrison, Forest Planner, Francis Marion National Forest at 803–561–4000. Individuals who use telecommunication devices for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1–800–877–8339 between 8:00 a.m. and 8:00 p.m. (Eastern time), Monday through Friday.

SUPPLEMENTARY INFORMATION: The Forest Service, Southern Region, Francis Marion National Forest, has prepared a Revised Land Mangement Plan, Final Environmental Impact Statement, and a Draft Record of Decision. This notice is to inform the public that a 60-day period is being initiated where individuals or entities with specific concerns on the Francis Marion's Revised Land Management Plan and its associated Final Environmental Impact Statement may file an objection for a Forest Service review prior to the approval of the Revised Land Management Plan. The publication date of the legal notice in the Francis Marion and Sumter National Forests newspaper of record, *The State,* will initiate the 60-day objection period and is the exclusive means for calculating the time to file an objection (36 CFR 219.16 and 219.52). An electronic scan of the notice with the publication date will be posted at the Francis Marion National Forest Web site at: *http://www.fs.usda.gov/detail/scnfs/landmanagement/planning/?cid=stelprdb5393142.*

The objection process under 36 CFR 219 subpart B, provides an opportunity for members of the public who have participated in the planning process for the Francis Marion National Forest to have any unresolved concerns reviewed by the Forest Service prior to a final decision by the Responsible Official. Only those who provided substantive formal comments during opportunities for public comment during the planning process are eligible to file an objection. Regulations at 36 CFR 219.62 define substantive formal comments as:

> "Written comments submitted to, or oral comments recorded by, the responsible official or his designee during an opportunity for public participation provided during the planning process, and attributed to the individual or entity providing them. Comments are considered substantive when they are within the scope of the proposal, are specific to the proposal, have a direct relationship to the proposal, and include supporting reasons for the responsible official to consider."

How to File an Objection

The Forest Service will accept mailed, emailed, faxed, and hand-delivered objections concerning the Revised Land Management Plan and associated Final Environmental Impact Statement for 60 calendar days following the date of the publication of the legal notice of this objection period in newspaper of record, *The State.* It is the responsibility of the objector to ensure that the Reviewing Officer receives the objection in a timely manner. The regulations prohibit extending the length of the objection filing period.

Objections must be submitted to the Reviewing Officer, who will be Tony Tooke, Regional Forester for the Southern Region, at the address shown in the **ADDRESSES** section of this notice. Objections or objection content specific to the identification of species of conservation concern will be forwarded to Brian Ferebee, Associate Deputy Chief, delegated Reviewing Officer for the Chief of the Forest Service.

An objection must include the following (36 CFR 219.54(c)):

(1) The objector's name and address along with a telephone number or email address if available—in cases where no

identifiable name is attached to an objection, the Forest Service will attempt to verify the identity of the objector to confirm objection eligibility;

(2) Signature or other verification of authorship upon request (a scanned signature for electronic mail may be filed with the objection);

(3) Identification of the lead objector, when multiple names are listed on an objection. The Forest Service will communicate to all parties to an objection through the lead objector. Verification of the identity of the lead objector must also be provided if requested;

(4) The name of the plan revision being objected to, and the name and title of the Responsible Official;

(5) A statement of the issues and/or parts of the plan revision to which the objection applies;

(6) A concise statement explaining the objection and suggesting how the proposed plan decision may be improved. If the objector believes that the plan revision is inconsistent with law, regulation, or policy, an explanation should be included;

(7) A statement that demonstrates the link between the objector's prior substantive formal comments and the content of the objection, unless the objection concerns an issue that arose after the opportunities for formal comment; and

(8) All documents referenced in the objection (a bibliography is not sufficient), except that the following need not be provided:

a. All or any part of a Federal law or regulation,

b. Forest Service Directive System documents and land management plans or other published Forest Service documents,

c. Documents referenced by the Forest Service in the planning documentation related to the proposal subject to objection, and

d. Formal comments previously provided to the Forest Service by the objector during the plan revision comment period.

Responsible Official

The responsible official for the revision of the land management plan for the Francis Marion National Forest is Rick Lint, Forest Supervisor, Francis Marion and Sumter National Forests, 4931 Broad River Road, Columbia, SC 29212.

Dated: August 10, 2016.

John Richard Lint,

Forest Supervisor.

[FR Doc. 2016–19608 Filed 8–16–16; 8:45 am]

BILLING CODE 3411–15–P

DEPARTMENT OF COMMERCE

[Docket No. 160714611–6611–01]

Office of Administration; Commerce Alternative Personnel System

AGENCY: Office of Administration, Office of Human Resources Management, Department of Commerce.

ACTION: Notice.

SUMMARY: This notice announces modifications to the provisions of the Commerce Alternative Personnel System, formerly the Department of Commerce Personnel Management Demonstration Project, published in the **Federal Register** on December 24, 1997.

As published on January 2, 2015 (80 FR 25), the Commerce Alternative Personnel System implemented direct-hire authority, under section 3304(a)(3) of Title 5 of the United States Code, for recruitment of certain scientific and engineering positions in the ZP career path at the Pay Band IV and above. Direct-hire authority was authorized for positions located in the National Telecommunications and Information Administration (NTIA), employed under the First Responder Network Authority (FirstNet). The System was modified again, as published on June 22, 2016 (81 FR 40653), to increase the number of positions FirstNet could fill under direct-hire authority and to include certain occupational series in the ZP career path at the Pay Band III level and above.

This notice serves to make changes to the System to expand the use of direct-hire authority to the NTIA, Institute for Telecommunication Sciences (ITS), and authorizes ITS to fill certain ZP positions, on a limited basis, at the Pay Band III level and above. This notice also serves to announce the addition of the 1520—Mathematics occupational series to the Commerce Alternative Personnel System.

DATES: The amended Commerce Alternative Personnel System is effective August 17, 2016.

FOR FURTHER INFORMATION CONTACT: Department of Commerce—Sandra Thompson, U.S. Department of Commerce, 14th and Constitution Avenue NW., Room 51020, Washington, DC 20230, (202) 482–0056 or Valerie Smith at (202) 482–0272.

SUPPLEMENTARY INFORMATION:

1. Background

The Office of Personnel Management (OPM) approved the Department of Commerce (DoC) demonstration project for an alternative personnel management system and published the approval of the final plan in the **Federal Register** on Wednesday, December 24, 1997 (62 FR 67434). The demonstration project was designed to simplify current classification systems allowing greater flexibility in classifying work and paying employees; establish a performance management and rewards system for improving individual and organizational performance; and improve recruiting and examining to attract highly-qualified candidates. The purpose of the project was to strengthen the contribution of human resources management and test whether the same innovations conducted under the National Institute of Standards and Technology alternative personnel management system would produce similarly successful results in other DoC environments. The project was implemented on March 29, 1998. The project plan has been modified ten times to clarify certain DoC Demonstration Project authorities, and to extend and expand the project: 64 FR 52810 (September 30, 1999); 68 FR 47948 (August 12, 2003); 68 FR 54505 (September 17, 2003); 70 FR 38732 (July 5, 2005); 71 FR 25615 (May 1, 2006); 71 FR 50950 (August 28, 2006); 74 FR 22728 (May 14, 2009); 80 FR 25 (January 2, 2015); 81 FR 20322 (April 7, 2016); 81 FR 40653 (June 22, 2016). With the passage of the Consolidated Appropriations Act, 2008, Public Law 110–161, on December 26, 2007, the project was made permanent (extended indefinitely) and renamed the Commerce Alternative Personnel System (CAPS).

CAPS provides for modifications to be made as experience is gained, results are analyzed, and conclusions are reached on how the system is working. This notice announces that the DoC implements ITS' use of direct-hire authority under 5 U.S.C. 3304(a)(3) to fill specific scientific and engineering positions announced through this notice in the ZP career path and adds the occupational series: 1520—Mathematics to the ZP career path. The DoC will follow the CAPS plan, as published in the **Federal Register** on December 24, 1997, and subsequent modifications as listed in the Background Section of this notice.

Kevin E. Mahoney,

Director for Human Resources Management and Chief Human Capital Officer.

Table of Contents

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II. Basis for CAPS Expansion
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I. Executive Summary

CAPS is designed to (1) improve hiring and allow DoC to compete more effectively for high-quality candidates through direct hiring, selective use of higher entry salaries, and selective use of recruitment incentives; (2) motivate and retain staff through higher pay potential, pay-for-performance, more responsive personnel systems, and selective use of retention incentives; (3) strengthen the manager's role in personnel management through delegation of personnel authorities; and (4) increase the efficiency of personnel systems through the installation of a simpler and more flexible classification system based on pay banding through reduction of guidelines, steps, and paperwork in classification, hiring, and other personnel systems, and through automation.

The current participating organizations include 7 offices of the Chief Financial Officer/Assistant Secretary for Administration in the Office of the Secretary; the Bureau of Economic Analysis; the Institute for Telecommunication Sciences—National Telecommunications and Information Administration; the First Responder Network Authority—National Telecommunications and Information Administration; and 12 units of the National Oceanic and Atmospheric Administration: Office of Oceanic and Atmospheric Research, National Marine Fisheries Service, the National Environmental Satellite, Data, and Information Service, National Weather Service—Space Environment Center, National Ocean Service, Program Planning and Integration Office, Office of the Under Secretary, Marine and Aviation Operations, Office of the Chief Administrative Officer, Office of the Chief Financial Officer, the Workforce Management Office, and the Office of the Chief Information Officer.

This amendment modifies the June 22, 2016, **Federal Register** notice (81 FR 40653). Specifically, it expands and implements direct-hire authority for ITS and enables ITS to hire, after public notice is given, any qualified applicants in the ZP career path series as defined in the Basis for CAPS Expansion section without regard to 5 U.S.C. 3309–3318, 5 CFR part 211, or 5 CFR part 337, subpart A on a limited basis.

II. Basis for CAPS Expansion

A. Purpose

CAPS is designed to provide managers at the lowest organizational level the authority, control, and flexibility to recruit, retain, develop, recognize, and motivate its workforce, while ensuring adequate accountability and oversight.

ITS is responsible for providing core telecommunications research and engineering services to promote enhanced domestic competition and new technology deployment; advancing telecommunications and information services; improving foreign trade opportunities for U.S. telecommunication firms and more efficient use of the radio frequency spectrum. ITS also serves as a principal Federal resource for investigating the telecommunications challenges of other Federal agencies, state and local governments, private corporations and associations, and international organizations. In particular, this includes assisting Federal public safety agencies, the Federal Communications Commission, and agencies that use Federal spectrum. As specified in the June 28, 2010, Presidential Memorandum, "Unleashing the Wireless Broadband Revolution" NTIA is responsible for exploring innovative spectrum-sharing technologies. As the research and engineering laboratory for NTIA, ITS supports NTIA by performing research that enables the U.S. Government, national and international standards organizations, and many aspects of private industry to manage the radio spectrum and ensure that innovative, new technologies are recognized and effective. To continue to advance strategic initiatives to make additional spectrum available for commercial wireless use and to meet the increasing radio spectrum needs of both Federal and commercial users in the U.S. as efficiently and effectively as possible, ITS must quickly hire qualified individuals, for specialized roles, to advance communication technologies.

Section 3304(a)(3) of Title 5 United States Code provides agencies with the authority to appoint candidates directly to jobs for which the OPM determines that there is a severe shortage of candidates or a critical hiring need. OPM's direct-hire authority enables agencies to hire, after public notice is given, any qualified applicant without regard to 5 U.S.C. 3309–3318, 5 CFR part 211, or 5 CFR part 337, subpart A.

This notice implements ITS' use of direct-hire authority to fill up to 20 positions in the ZP career path, at Pay Band III or higher, in the following occupational series: 0854—Computer Engineering; 0855—Electronics Engineering; 1310—Physics; 1550—Computer Science; or 1520—Mathematics. The use of direct-hire authority to fill these positions will not exceed 20 positions in the ZP career path at any one time. ITS will track the number of hires made under direct-hire authority, ensuring numbers specified for the occupational series are not exceeded.

In 1997, with the approval of the DoC's Demonstration Project (62 FR 67434, December 24, 1997), OPM concurred that some occupations in the ZP career path at the Pay Band III and above constitute a shortage category, and some occupations for which there is a special rate under the General Schedule pay system constitute a shortage category. Past recruitment efforts have demonstrated a critical shortage of candidates possessing specialized technical expertise in spectrum measurements, spectrum monitoring, propagation modeling, 4G Long Term Evolution (LTE) technologies, mobile systems development, computer security, systems engineering, scientific software development, as well as expertise in public safety organizational operations and infrastructure capabilities. ITS will use direct-hire authority to recruit Computer Engineers, Electronics Engineers, Computer Scientists, Physicists and Mathematicians in the ZP career path, Pay Band III or higher, with efforts focused on recruiting individuals possessing the above listed specialized technical areas of expertise. Recruitment of individuals possessing this expertise is critical in order to measure, analyze, monitor, and evaluate cutting edge technologies and methods that will make spectrum sharing possible.

DoC's CAPS allows for modifications of procedures if no new waiver from law or regulation is added. Given that this expansion and modification is in accordance with existing law and regulation and CAPS is a permanent alternative personnel system, the DoC is authorized to make the changes described in this notice.

III. Changes to the Project Plan

The CAPS at DoC, originally published in the **Federal Register** on December 24, 1997 (62 FR 67434), and subsequently expanded as discussed above, Section III (81 FR 40653, June 22, 2016), is modified as follows:

1. The following series is added to Table 2:

Scientific and Engineering (ZP) Career Path 1520, Mathematics Series

2. Section III Personnel System Changes, (B) Staffing: Replace the paragraph in subsection titled: "Direct-Hire Authority: Critical Shortage Occupations" to state:

DoC FirstNet and ITS use direct-hire procedures for categories of occupations that require skills that are in short supply. The following occupations and series constitute a shortage category at the Pay Band III and above in the ZP Career Path: Emergency Management Specialists (Public Safety) (0089), Electrical Engineers (0850), Computer Engineers (0854), Electronics Engineers, (0855), Physicists (1310), Computer Scientists (1550), and Mathematicians (1520). FirstNet is authorized to fill positions in the following occupational series using direct-hire procedures: 0089, 0850, 0854, 0855, and 1550 in all duty locations. ITS is authorized to fill positions in the following occupational series: 0854, 0855, 1310, 1550, and 1520 in all duty locations. Positions in these categories may be filled by FirstNet and ITS through direct-hire procedures in accordance with 5 U.S.C. 3304(a)(3). DoC FirstNet and ITS advertise the availability of job opportunities in direct-hire occupations by posting on the OPM USAJOBS Web site. DoC FirstNet and ITS will follow internal direct-hire procedures for accepting applications.

[FR Doc. 2016–19616 Filed 8–16–16; 8:45 am]

BILLING CODE 3510–EA–P

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[S–75–2016]

Approval of Subzone Status: Westlake Chemical Corporation, Geismar, Louisiana

On May 25, 2016, the Executive Secretary of the Foreign-Trade Zones (FTZ) Board docketed an application submitted by the Greater Baton Rouge Port Commission, grantee of FTZ 154, requesting subzone status subject to the existing activation limit of FTZ 154, on behalf of Westlake Chemical Corporation in Geismar, Louisiana.

The application was processed in accordance with the FTZ Act and Regulations, including notice in the **Federal Register** inviting public comment (81 FR 35297, June 2, 2016). The FTZ staff examiner reviewed the application and determined that it meets the criteria for approval.

Pursuant to the authority delegated to the FTZ Board's Executive Secretary (15 CFR Sec. 400.36(f)), the application to establish Subzone 154C is approved, subject to the FTZ Act and the Board's regulations, including Section 400.13, and further subject to FTZ 154's 2,000-acre activation limit.

Dated: August 11, 2016.

Andrew McGilvray,

Executive Secretary.

[FR Doc. 2016–19647 Filed 8–16–16; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

Industry and Security Bureau

Submission for OMB Review; Comment Request

The Department of Commerce will submit to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of Industry and Security.

Title: International Import Certificate.

Form Number(s): BIS–645P.

OMB Control Number: 0694–0017.

Type of Request: Regular.

Burden Hours: 52 hours.

Number of Respondents: 195 respondents.

Average Hours per Response: 16 minutes per response.

Needs and Uses: The United States and several other countries have increased the effectiveness of their respective controls over international trade in strategic commodities by means of an Import Certificate procedure. For the U.S. importer, this procedure provides that, where required by the exporting country, the importer submits an international import certificate to the U.S. Government to certify that he/she will import commodities into the United States and will not reexport such commodities, except in accordance with the export control regulations of the United States. The U.S. Government, in turn, certifies that such representations have been made.

Affected Public: Businesses and other for-profit institutions.

Frequency: On occasion.

Respondent's Obligation: Required to obtain benefits.

This information collection request may be viewed at *www.reginfo.gov.* Follow the instructions to view the Department of Commerce collections currently under review by OMB.

Written comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to OIRA *Submission@omb.eop.gov* or fax to (202) 395–5806.

Dated: August 11, 2016.

Glenna Mickelson,

Management Analyst, Office of the Chief Information Officer.

[FR Doc. 2016–19517 Filed 8–16–16; 8:45 am]

BILLING CODE 3510–33–P

BUREAU OF CONSUMER FINANCIAL PROTECTION

Credit Union Advisory Council Meeting

AGENCY: Bureau of Consumer Financial Protection.

ACTION: Notice of public meeting.

SUMMARY: This notice sets forth the announcement of a public meeting of the Credit Union Advisory Council (CUAC or Council) of the Consumer Financial Protection Bureau (CFPB or Bureau). The notice also describes the functions of the Council. Notice of the meeting is permitted by section 9 of the CUAC Charter and is intended to notify the public of this meeting. Specifically, section 9(d) of the CUAC Charter states:

> (1) Each meeting of the Council shall be open to public observation, to the extent that a facility is available to accommodate the public, unless the Bureau, in accordance with paragraph (4) of this section, determines that the meeting shall be closed. The Bureau also will make reasonable efforts to make the meetings available to the public through live recording. (2) Notice of the time, place and purpose of each meeting, as well as a summary of the proposed agenda, shall be published in the **Federal Register** not more than 45 or less than 15 days prior to the scheduled meeting date. Shorter notice may be given when the Bureau determines that the Council's business so requires; in such event, the public will be given notice at the earliest practicable time. (3) Minutes of meetings, records, reports, studies, and agenda of the Council shall be posted on the Bureau's Web site (*www.consumerfinance.gov*). (4) The Bureau may close to the public a portion of any meeting, for confidential discussion. If the Bureau closes a meeting or any portion of a meeting, the Bureau will issue, at least annually, a summary of the Council's activities during such closed meetings or portions of meetings.

DATES: The meeting date is Thursday, September 1, 2016, 3:30 p.m. to 5:00 p.m. eastern daylight time.

ADDRESSES: The meeting location is the Consumer Financial Protection Bureau, 1275 First Street NE., Washington, DC 20002.

FOR FURTHER INFORMATION CONTACT: Crystal Dully, Outreach and Engagement Associate, 202–435–9588, *CFPB_CABandCouncilsEvents@cfpb.gov,* Consumer Advisory Board and Councils Office, External Affairs, 1275 First Street NE., Washington, DC 20002.

SUPPLEMENTARY INFORMATION:

I. Background

Section 2 of the CUAC Charter provides: "Pursuant to the executive and administrative powers conferred on the Consumer Financial Protection Bureau by section 1012 of the Dodd-

Frank Wall Street Reform and Consumer Protection Act (Dodd-Frank Act), the Director established the Credit Union Advisory Council to consult with the Bureau in the exercise of its functions under the Federal consumer financial laws as they pertain to credit unions with total assets of $10 billion or less.''

Section 3 of the CUAC Charter states: ''a) The CFPB supervises depository institutions and credit unions with total assets of more than $10 billion and their respective affiliates, but other than the limited authority conferred by section 1026 of the Dodd-Frank Act, the CFPB does not have supervisory authority regarding credit unions and depository institutions with total assets of $10 billion or less. As a result, the CFPB does not have regular contact with these institutions, and it would therefore be beneficial to create a mechanism to ensure that their unique perspectives are shared with the Bureau. Small Business Regulatory Enforcement Fairness Act (SBREFA) panels provide one avenue to gather this input, but participants from credit unions must possess no more than $175 million in assets, which precludes the participation of many. b) The Advisory Council shall fill this gap by providing an interactive dialogue and exchange of ideas and experiences between credit union employees and Bureau staff. c) The Advisory Council shall advise generally on the Bureau's regulation of consumer financial products or services and other topics assigned to it by the Director. To carry out the Advisory Council's purpose, the scope of its activities shall include providing information, analysis, and recommendations to the Bureau. The output of Advisory Council meetings should serve to better inform the CFPB's policy development, rulemaking, and engagement functions.''

II. Agenda

The Credit Union Advisory Council will discuss youth financial capability and debt collection. Persons who need a reasonable accommodation to participate should contact *CFPB_504Request@cfpb.gov,* 202–435–9EEO, 1–855–233–0362, or 202–435–9742 (TTY) at least ten business days prior to the meeting or event to request assistance. The request must identify the date, time, location, and title of the meeting or event, the nature of the assistance requested, and contact information for the requester. CFPB will strive to provide, but cannot guarantee that accommodation will be provided for late requests.

Individuals who wish to attend the Credit Union Advisory Council meeting must RSVP to *cfpb_cabandcouncilsevents@cfpb.gov* by noon, Wednesday, August 31, 2016. Members of the public must RSVP by the due date and must include ''CUAC'' in the subject line of the RSVP.

III. Availability

The Council's agenda will be made available to the public on Wednesday, August 17, 2016, via *consumerfinance.gov.* Individuals should express in their RSVP if they require a paper copy of the agenda.

A recording and transcript of this meeting will be available after the meeting on the CFPB's Web site *consumerfinance.gov.*

Dated: August 11, 2016.

Christopher D'Angelo,

Chief of Staff, Bureau of Consumer Financial Protection.

[FR Doc. 2016–19622 Filed 8–16–16; 8:45 am]

BILLING CODE 4810–AM–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID: DOD–2016–OS–0086]

Notice of Availability (NOA) of an Environmental Assessment (EA) Addressing Defense Logistics Agency Disposition Services Relocation and Expansion at Defense Supply Center, Richmond, Virginia

AGENCY: Defense Logistics Agency (DLA), Department of Defense.

ACTION: Notice of Availability (NOA) of an Environmental Assessment (EA) Addressing Defense Logistics Agency Disposition Services Relocation and Expansion at Defense Supply Center, Richmond, Virginia.

SUMMARY: Defense Logistics Agency (DLA) announces the availability of an environmental assessment (EA) documenting the potential environmental effects associated with the Proposed Action to relocate and expand DLA Disposition Services at Richmond, which is at Defense Supply Center, Richmond, Virginia. The EA has been prepared as required under the National Environmental Policy Act (NEPA) (1969). In addition, the EA complies with DLA Regulation 1000.22. DLA has determined that the Proposed Action would not have a significant impact on the human environment within the context of NEPA. Therefore, the preparation of an environmental impact statement is not required.

DATES: The public comment period will end on September 16, 2016. Comments received by the end of the 30-day period will be considered when preparing the final version of the document. The Draft EA is available electronically at the Federal eRulemaking Portal at *http://www.regulations.gov,* and in hardcopy at the main branch of the Chesterfield Central Library, 9501 Lori Road, Chesterfield, VA 23832.

ADDRESSES: You may submit comments to one of the following:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Department of Defense, Office of the Deputy Chief Management Officer, Directorate for Oversight and Compliance, 4800 Mark Center Drive, Mailbox #24, Alexandria, VA 22350–1700.

FOR FURTHER INFORMATION CONTACT: Ira Silverberg at 703–767–0705 during normal business hours Monday through Friday, from 8:00 a.m. to 4:30 p.m. (EDT) or by email: *ira.silverberg@dla.mil.*

Dated: August 11, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19558 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Department of Defense Military Family Readiness Council (MFRC); Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce a Federal Advisory Committee meeting of the Department of Defense Military Family Readiness Council. This meeting will be open to the public.

DATES: Wednesday, September 14, 2016, from 1:00 p.m. to 3:00 p.m.

ADDRESSES: Pentagon Conference Center Room B6 (escorts will be provided from the Pentagon Metro entrance).

FOR FURTHER INFORMATION CONTACT: Ms. Melody McDonald or Ms. Betsy Graham, Office of the Deputy Assistant Secretary of Defense (Military Community & Family Policy), Office of Family Readiness Policy, 4800 Mark Center Drive Alexandria, VA 22350–2300, Room 3G15. Telephones (571) 372–0880; (571) 372–0881 and/or email: OSD Pentagon OUSD P–R Mailbox Family Readiness Council, *osd.pentagon.ousd-*

p-r.mbx.family-readiness-council@mail.mil.

SUPPLEMENTARY INFORMATION:

This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. The purpose of the Council is to review and make recommendations to the Secretary of Defense regarding policy and plans supporting military family readiness; monitor requirements for the support of military family readiness by the Department of Defense; and evaluate and assess the effectiveness of the military family readiness programs and activities of the Department of Defense.

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, this meeting is open to the public, subject to the availability of space. Members of the public who are entering the Pentagon should arrive at the visitor center next to the Metro entrance 30 minutes before the scheduled meeting time to allow time to pass through the security check points. Members of the public need to email the Council at *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil* no later than 5:00 p.m., on Thursday, September 8, 2016 to arrange for an escort from the security check point to the Conference Room area. Pursuant to 41 CFR 102–3.105(j) and 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, interested persons may submit a written statement for consideration by the Council. Persons desiring to submit a written statement to the Council must submit to the email address *osd.pentagon.ousd-p-r.mbx.family-readiness-council@mail.mil,* no later than 5:00 p.m., on Wednesday, September 7, 2016.

The purpose of this meeting is to develop Fiscal Year 2016 recommendations for the Secretary of Defense regarding topics discussed at the June 16, 2016 meeting of the Council, including military family health and family financial readiness; and to determine Council focus items for Fiscal Year 2017.

Wednesday, September 14, 2016
Meeting Agenda

Welcome & Administrative Remarks

Discuss and develop recommendations concerning military family health and family financial readiness

Discuss focus items for FY2017

Closing Remarks

Note: Exact order may vary

Dated: August 12, 2016.

Aaron Siegel,

Alternate OSD **Federal Register** *Liaison Officer, Department of Defense.*

[FR Doc. 2016–19635 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

National Security Education Board; Notice of Federal Advisory Committee Meeting

AGENCY: The Office of the Under Secretary of Defense for Personnel and Readiness, Defense Language and National Security Education Office (DLNSEO), DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce that the following Federal advisory committee meeting of the National Security Education Board (NSEB) will take place. This meeting is open to the public.

DATES: Thursday, September 8, 2016, from 10:30 a.m. to 4:45 p.m.

ADDRESSES: Capital Hilton Hotel, 1001 16th Street NW., Washington, DC 20036.

FOR FURTHER INFORMATION CONTACT: Alison Patz, telephone (571) 256–0771, *Alison.m.patz.civ@mail.mil,* fax (703) 692–2615.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of the meeting is to review and make recommendations to the Secretary of Defense concerning requirements established by the David L. Boren National Security Education Act, Title VII of Public Law 102–183, as amended.

Agenda:

10:30 a.m.—Opening Remarks and Key Updates.
10:45 a.m.—Board's Role in the National Language Service Corps.
11:30 a.m.—Integrating Culture into the Language Classroom.
12:30 p.m.—Working Lunch.
2:00 p.m.—Flagship Recruitment: Best Practices.
3:00 p.m.—Break.
3:15 p.m.—Updates on Diversity.
3:30 p.m.—NSEP Awardees and the Security Clearance Process.
4:15 p.m.—Board Discussion.
4:45 p.m.—Adjourn.

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

Committee's Point of Contact: Alison Patz, Alternate Designated Federal Official, (571) 256–0771, *Alison.m.patz.civ@mail.mil.*

Pursuant to 102–3.140 and sections 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Department of Defense National Security Education Board about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of the planned meeting.

All written statements shall be submitted to the Designated Federal Official for the National Security Education Board, and this individual will ensure that the written statements are provided to the membership for their consideration. Contact information for the Designated Federal Official can be obtained from the GSA's FACA Database—*http://facadatabase.gov/.*

Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Official at the address listed in **FOR FURTHER INFORMATION CONTACT** at least five calendar days prior to the meeting that is the subject of this notice. Written statements received after this date may not be provided to or considered by the National Security Education Board until its next meeting.

The Designated Federal Official will review all timely submissions with the National Security Education Board and ensure they are provided to all members of the National Security Education Board before the meeting that is the subject of this notice.

Dated: August 12, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19605 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Defense Acquisition University Board of Visitors; Notice of Federal Advisory Committee Meeting

AGENCY: Defense Acquisition University, DoD.

ACTION: Meeting notice.

SUMMARY: The Department of Defense is publishing this notice to announce a Federal Advisory Committee meeting of the Defense Acquisition University Board of Visitors. This meeting will be open to the public.

DATES: Wednesday, September 14, 2016, from 9:00 a.m. to 4:00 p.m.

ADDRESSES: DAU Headquarters, Bldg. 202, 9820 Belvoir Road, Ft. Belvoir, VA 22060.

FOR FURTHER INFORMATION CONTACT: Caren Hergenroeder, Protocol Director, DAU. Phone: 703–805–5134. Fax: 703–805–5940. Email: *caren.hergenroeder@dau.mil.*

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C., Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150.

Purpose of the Meeting: The purpose of this meeting is to report back to the Board of Visitors on continuing items of interest.

Agenda

9:00 a.m. Welcome and Announcements
9:05 a.m. Dialogue with Industry Representatives
11:00 a.m. Board Discussion
12:00 p.m. Lunch
1:00 p.m. Feedback Session: Scenario-based Strategic Planning
1:30 p.m. Transition Planning
2:00 p.m. DAU Update
3:30 p.m. Summary Discussion
4:00 p.m. Adjourn

Public's Accessibility to the Meeting: Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. However, because of space limitations, allocation of seating will be made on a first-come, first served basis. Persons desiring to attend the meeting should call Ms. Caren Hergenroeder at 703–805–5134.

Written Statements: Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Defense Acquisition University Board of Visitors about its mission and functions. Written statements may be submitted at any time or in response to the stated agenda of a planned meeting of the Defense Acquisition University Board of Visitors.

All written statements shall be submitted to the Designated Federal Officer for the Defense Acquisition University Board of Visitors, and this individual will ensure that the written statements are provided to the membership for their consideration.

Statements being submitted in response to the agenda mentioned in this notice must be received by the Designated Federal Officer at least five calendar days prior to the meeting which is the subject of this notice. Written statements received after this date may not be provided to or considered by the Defense Acquisition University Board of Visitors until its next meeting. Committee's Designated Federal Officer or Point of Contact: Ms. Christen Goulding, 703–805–5412, *christen.goulding@dau.mil.*

Dated: August 11, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19565 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

Strategic Environmental Research and Development Program, Scientific Advisory Board; Notice of Federal Advisory Committee Meeting

AGENCY: Department of Defense.

ACTION: Notice.

SUMMARY: The Department of Defense is publishing this notice to announce an open meeting of the Strategic Environmental Research and Development Program, Scientific Advisory Board (SAB). This meeting will be open to the public.

DATES: Tuesday, September 13, 2016, from 9:00 a.m. to 4:40 p.m. and Wednesday, September 14, 2016, from 8:30 a.m. to 4:15 p.m.

ADDRESSES: 901 N. Stuart Street Suite 200, Arlington, VA 22203.

FOR FURTHER INFORMATION CONTACT: Dr. Herb Nelson, SERDP Office, 4800 Mark Center Drive, Suite 17D08, Alexandria, VA 22350–3605; or by telephone at (571) 372–6565.

SUPPLEMENTARY INFORMATION: This meeting is being held under the provisions of the Federal Advisory Committee Act of 1972 (5 U.S.C. Appendix, as amended), the Government in the Sunshine Act of 1976 (5 U.S.C. 552b, as amended), and 41 CFR 102–3.150. This notice is published in accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463).

Pursuant to 5 U.S.C. 552b and 41 CFR 102–3.140 through 102–3.165, and the availability of space, this meeting is open to the public. Seating is on a first-come basis.

The purpose of the September 13–14, 2016 meeting is to review new start research and development projects requesting Strategic Environmental Research and Development Program funds as required by the SERDP Statute, U.S. Code—Title 10, Subtitle A, Part IV, Chapter 172, § 2904. The full agenda follows:

Agenda for September 13, 2016.

9:10 a.m.	Program Update	Dr. Herb Nelson, Acting Executive Director.
9:25 a.m.	Munitions Response Overview	Dr. Herb Nelson, Munitions Response, Program Manager.
9:30 a.m.	17 MR01–008 (MR–2728): Enhanced EMI Models and Systems for Underwater UXO Detection and Discrimination (FY17 New Start).	Dr. Fridon Shubitidze, Dartmouth College, Hanover, NH.
10:15 a.m.	Munitions Response Overview	Dr. Herb Nelson, Munitions Response, Program Manager.
10:25 a.m.	17 MR01–009 (MR–2729): Rapid Response Surveys of Mobility, Burial and Re-Exposure of Underwater Munitions in Energetic Surf-Zone Environments and Object Monitoring Technology Development (FY17 New Start).	Dr. Peter Traykovski, Woods Hole Oceanographic Institution, Woods Hole, MA.
11:10 a.m.	Break	
11:25 a.m.	17 MR01–023 (MR–2732): Three-Dimensional Computational Modeling of Turbulent Flow Field, Bed Morphodynamics and Liquefaction Adjacent to Munitions, (FY17 New Start).	Dr. Xiaofeng Liu, Pennsylvania State University, University Park, PA.

12:10 p.m.	Lunch	
1:10 p.m.	17 MR01–021 (MR–2731): Resolving the Role of the Dynamic Pressure in the Burial, Exposure, Scour, and Mobility of Underwater Munitions (FY17 New Start).	Dr. Diane Foster, University of New Hampshire, Durham, NH.
1:55 p.m.	Munitions Response Overview	Dr. Herb Nelson, Munitions Response, Program Manager.
2:00 p.m.	17 MR01–027 (MR–2733): Probabilistic Environmental Forecasting System for Munitions Mobility (FY17 New Start).	Dr. Margaret Palmsten, Naval Research Laboratory, Stennis Space Center, MS.
2:45 p.m.	Break	
3:00 p.m.	Weapons Systems and Platforms Overview	Dr. Robin Nissan, Weapons Systems and Platforms, Program Manager.
3:10 p.m.	17 WP01–003 (WP- 2738): Fluorine-Free Aqueous Film Forming Foam (FY17 New Start).	Dr. John Payne, National Foam, West Chester, PA.
3:55 p.m.	17 WP01–005 (WP- 2739): Fluorine-Free Foams with Oleophobic Surfactants and Additives for Effective Pool Fire Suppression (FY17 New Start).	Dr. Ramagopal Ananth, U.S. Naval Research Laboratory, Washington, DC.
4:40 p.m.	Public Discussion/Adjourn for the day.	

Agenda for September 14, 2016

8:40 a.m.	Environmental Restoration Overview	Dr. Andrea Leeson, Environmental Restoration, Program Manager.
8:50 a.m.	17 ER02–015 (ER–2722): Development and Optimization of Analytical Methods for Simultaneous Determination of IM and Legacy Explosive Compounds, (FY17 New Start).	Dr. Anthony Bednar, U.S. Army Engineer Research and Development Center, Vicksburg, MS.
9:35 a.m.	17 ER03–026 (ER–2726): Application of Carbon and Nitrogen Stable Isotope Analysis to Evaluate Biotic and Abiotic Degradation of DNAN and NTO (FY17 New Start).	Dr. Neil Sturchio, University of Delaware, Newark, DE.
10:20 a.m.	Break	
10:35 a.m.	17 ER03–034 (ER–2727): Phototransformation, Sorption, Transport, and Fate of Mixtures of NTO, DNAN, and Traditional Explosives as a Function of Climatic Conditions (FY17 New Start).	Dr. Katerina Dontsova, University of Arizona, Tucson, AZ.
11:20 a.m.	17 ER03–013 (ER–2724): Determination of Fate and Toxicological Effects of Insensitive Munitions Compounds in Terrestrial Ecosystems (FY17 New Start).	Dr. Roman Kuperman, U.S. Army Edgewood Chemical Biological Center, Aberdeen Proving Ground, MD.
12:05 p.m.	Lunch	
1:05 p.m.	17 ER03–010 (ER–2723): Environmental Impact of DNAN and NTO on Plants, (FY17 New Start).	Mr. Timothy Cary, U.S. Army ERDC–CRREL, Hanover, NH.
1:50 p.m.	Resource Conservation & Climate Change Overview	Dr. Herb Nelson, Resource Conservation & Climate Change, Program Manager.
2:00 p.m.	17 RC01–063 (RC–2703): Variation in Phenological Shifts: How do Annual Cycles and Genetic Diversity Constrain or Enable Responses to Climate Change? (FY17 New Start).	Dr. Katherine O'Donnell, U.S. Geological Survey, Gainsville, FL.
2:45 p.m.	Break	
3:00 p.m.	17 RC01–035 (RC–2701): Incorporating Photoperiodism in Insect Phenology Models with Application for Biological Control of Weeds on Department of Defense Lands, (FY17 New Start).	Dr. Fritzi Grevstad, Oregon State University, Corvallis, OR.
3:45 p.m.	Strategy Session	Dr. Herb Nelson, Acting Executive Director.
4:05 p.m.	Public Discussion/Adjourn.	

Pursuant to 41 CFR 102–3.140, and section 10(a)(3) of the Federal Advisory Committee Act of 1972, the public or interested organizations may submit written statements to the Strategic Environmental Research and Development Program, Scientific Advisory Board. Written statements may be submitted to the committee at any time or in response to an approved meeting agenda.

All written statements shall be submitted to the Designated Federal Officer (DFO) for the Strategic Environmental Research and Development Program, Scientific Advisory Board. The DFO will ensure that the written statements are provided to the membership for their consideration. Contact information for the DFO can be obtained from the GSA's FACA Database at *http://www.facadatabase.gov/*.

Time is allotted at the close of each meeting day for the public to make comments. Oral comments are limited to 5 minutes per person.

Dated: August 12, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19610 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF DEFENSE

Office of the Secretary

[Docket ID DOD–2014–OS–0073]

Submission for OMB Review; Comment Request

ACTION: Notice.

SUMMARY: The Department of Defense has submitted to OMB for clearance, the following proposal for collection of information under the provisions of the Paperwork Reduction Act.

DATES: Consideration will be given to all comments received by September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Fred Licari, 571–372–0493.

SUPPLEMENTARY INFORMATION:

Title, Associated Form and OMB No: Department of Defense Application for Priority Rating for Production or Construction Equipment, DD Form 691, OMB Control Number 0704–0055.

Type of Request: Reinstatement, with change, of a previously approved collection for which approval has expired.

Number of Respondents: 610.

Responses per Respondent: 1.

Annual Responses: 610.

Average Burden per Response: 1 hour.

Annual Burden Hours: 610.

Needs and Uses: Executive Order 12919 delegates to DoD authority to require certain contracts and orders relating to approved Defense Programs to be accepted and performed on a preferential basis. This program helps contractors acquire industrial equipment in a timely manner, thereby facilitating development and support of weapons systems and other important Defense Programs.

Affected Public: Business or other for-profit.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain benefits.

OMB Desk Officer: Ms. Jasmeet Seehra.

Comments and recommendations on the proposed information collection should be emailed to Ms. Jasmeet Seehra, DoD Desk Officer, at *Oira_submission@omb.eop.gov.* Please identify the proposed information collection by DoD Desk Officer and the Docket ID number and title of the information collection.

You may also submit comments and recommendations, identified by Docket ID number and title, by the following method:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.

Instructions: All submissions received must include the agency name, Docket ID number and title for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

DOD Clearance Officer: Mr. Frederick Licari.

Written requests for copies of the information collection proposal should be sent to Mr. Licari at WHS/ESD Directives Division, 4800 Mark Center Drive, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Dated: August 11, 2016.

Aaron Siegel,

Alternate OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 2016–19555 Filed 8–16–16; 8:45 am]

BILLING CODE 5001–06–P

DEPARTMENT OF EDUCATION

[Docket No. ED–2016–ICCD–0090]

Agency Information Collection Activities; Submission to the Office of Management and Budget for Review and approval; Comment Request; Application for Grants Under the Upward Bound Program

AGENCY: Office of Postsecondary Education (OPE), Department of Education (ED).

ACTION: Notice.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. chapter 3501 *et seq.*), ED is proposing a reinstatement of a previously approved information collection.

DATES: Interested persons are invited to submit comments on or before September 16, 2016.

ADDRESSES: To access and review all the documents related to the information collection listed in this notice, please use *http://www.regulations.gov* by searching the Docket ID number ED–2016–ICCD–0090. Comments submitted in response to this notice should be submitted electronically through the Federal eRulemaking Portal at *http://www.regulations.gov* by selecting the Docket ID number or via postal mail, commercial delivery, or hand delivery. *Please note that comments submitted by fax or email and those submitted after the comment period will not be accepted.* Written requests for information or comments submitted by postal mail or delivery should be addressed to the Director of the Information Collection Clearance Division, U.S. Department of Education, 400 Maryland Avenue SW., LBJ, Room 2E–347, Washington, DC 20202–4537.

FOR FURTHER INFORMATION CONTACT: For specific questions related to collection activities, please contact Ken Waters, 202–453–6273.

SUPPLEMENTARY INFORMATION: The Department of Education (ED), in accordance with the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3506(c)(2)(A)), provides the general public and Federal agencies with an opportunity to comment on proposed, revised, and continuing collections of information. This helps the Department assess the impact of its information collection requirements and minimize the public's reporting burden. It also helps the public understand the Department's information collection requirements and provide the requested data in the desired format. ED is soliciting comments on the proposed information collection request (ICR) that is described below. The Department of Education is especially interested in public comment addressing the following issues: (1) Is this collection necessary to the proper functions of the Department; (2) will this information be processed and used in a timely manner; (3) is the estimate of burden accurate; (4) how might the Department enhance the quality, utility, and clarity of the information to be collected; and (5) how might the Department minimize the burden of this collection on the respondents, including through the use of information technology. Please note that written comments received in response to this notice will be considered public records.

Title of Collection: Application for Grants Under the Upward Bound Program.

OMB Control Number: 1840–0550.

Type of Review: A reinstatement of a previously approved information collection.

Respondents/Affected Public: State, Local, and Tribal Governments; Private Sector.

Total Estimated Number of Annual Responses: 1,240.

Total Estimated Number of Annual Burden Hours: 40,880.

Abstract: The Department of Education is requesting a reinstatement with change of the application for grants under the Upward Bound (UB) Program. The Department is requesting a reinstatement with change because the previous UB application was discontinued in September 2014 and the application will be needed for a Fiscal Year (FY) 2017 competition for new awards. The FY 2017 application incorporates a competitive preference priority and an invitational priority and removes previously-used competitive preference priorities.

Dated: August 12, 2016.

Kate Mullan,

Acting Director, Information Collection Clearance Division, Office of the Chief Privacy Officer, Office of Management.

[FR Doc. 2016–19609 Filed 8–16–16; 8:45 am]

BILLING CODE 4000–01–P

DEPARTMENT OF ENERGY

Environmental Management Site-Specific Advisory Board, Paducah

AGENCY: Department of Energy.

ACTION: Notice of cancellation of open meeting.

SUMMARY: On August 2, 2016, the Department of Energy (DOE) published a notice of open meeting announcing a meeting on August 18, 2016, of the Environmental Management Site-Specific Advisory Board, Paducah. This notice announces the cancellation of this meeting. The meeting is being cancelled because the board will not have a quorum due to scheduling conflicts by members. The next regular meeting will be held on September 15, 2016.

DATES: The meeting scheduled for August 18, 2016, announced in the August 2, 2016, issue of the **Federal Register** (FR Doc. 2016–18186, 81 FR 50693), is cancelled. The next regular meeting will be held on September 15, 2016.

FOR FURTHER INFORMATION CONTACT: Jennifer Woodard, Deputy Designated Federal Officer, Department of Energy Paducah Site Office, Post Office Box 1410, MS–103, Paducah, Kentucky 42001, (270) 441–6825.

Issued at Washington, DC, on August 11, 2016.

LaTanya R. Butler,

Deputy Committee Management Officer.

[FR Doc. 2016–19529 Filed 8–16–16; 8:45 am]

BILLING CODE 6405–01–P

DEPARTMENT OF ENERGY

[FE Docket No. 16–98–LNG]

Carib Energy (USA) LLC; Application for Long-Term, Multi-Contract Authorization To Export Liquefied Natural Gas to Non-Free Trade Agreement Nations in Central America, South America, or the Caribbean

AGENCY: Office of Fossil Energy, DOE.

ACTION: Notice of application.

SUMMARY: The Office of Fossil Energy (FE) of the Department of Energy (DOE) gives notice of receipt of an application, filed on March 25, 2016 (Application), by Carib Energy (USA) LLC (Carib). Carib requests long-term, multi-contract authorization to export domestically produced liquefied natural gas (LNG) in a volume equivalent to approximately 1.3 billion cubic feet (Bcf) per year (0.0036 Bcf per day) of natural gas.[1] Carib Energy seeks to export the LNG by use of approved IMO7/TVAC–ASME LNG (ISO) containers transported on ocean-going carriers to any country within Central America, South America, or the Caribbean that has, or in the future develops, the capacity to import LNG delivered by ocean-going container vessels carrying ISO containers,[2] provided that trade is not prohibited by U.S. law or policy with that country, and provided further that the country has not entered into a free trade agreement with the United States requiring national treatment for trade in natural gas (non-FTA countries). Carib seeks to purchase the LNG for export from any of the existing natural gas liquefaction facilities listed in Appendix D of the Application (Facilities),[3] which are owned and operated by Pivotal LNG, Inc. (Pivotal) or by one of Pivotal's affiliates.[4] Carib states that delivery of LNG will be taken at the Facilities, and the LNG transported within the United States over highways using approved ISO containers. Carib intends to export the LNG from the ports of Jacksonville, Florida; Port Everglades, Florida; Gulfport, Mississippi; and any port in the southeastern United States capable of accommodating LNG exports by ISO containers transported on ocean-going container vessels. Carib seeks authorization to export this LNG for a 20-year period, commencing on the earlier of the date of first export or five years from the date the requested authorization is granted. The Application was filed under section 3 of the Natural Gas Act (NGA). Additional details can be found in Carib's Application, posted on the DOE/FE Web site at: *http://energy.gov/sites/prod/files/2016/07/f33/CaribEnergy16_98_LNGapp.pdf.*

Protests, motions to intervene, notices of intervention, and written comments are invited.

DATES: Protests, motions to intervene or notices of intervention, as applicable, requests for additional procedures, and written comments are to be filed using procedures detailed in the Public Comment Procedures section no later than 4:30 p.m., Eastern time, October 17, 2016.

ADDRESSES:

Electronic Filing by email: fergas@hq.doe.gov.

Regular Mail: U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, P.O. Box 44375, Washington, DC 20026–4375.

Hand Delivery or Private Delivery Services (e.g., FedEx, UPS, etc.): U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT:

Beverly Howard, or Larine Moore, U.S. Department of Energy (FE–34), Office of Regulation and International Engagement, Office of Fossil Energy, Forrestal Building, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–9387; (202) 586–9478.

Edward Myers, U.S. Department of Energy (GC–76), Office of the Assistant General Counsel for Electricity and Fossil Energy, Forrestal Building, 1000 Independence Avenue SW., Washington, DC 20585, (202) 586–3397.

SUPPLEMENTARY INFORMATION:

DOE/FE Evaluation

The Application will be reviewed pursuant to section 3(a) of the NGA, 15 U.S.C. 717b(a), and DOE will consider any issues required by law or policy. To the extent determined to be relevant, these issues will include the domestic need for the natural gas proposed to be exported, the adequacy of domestic natural gas supply, and U.S. energy security. DOE may also consider other factors bearing on the public interest, including the impact of the proposed exports on the U.S. economy, international considerations, and whether the authorization is consistent with DOE's policy of promoting competition in the marketplace by allowing commercial parties to freely negotiate their own trade arrangements. As part of this analysis, DOE will consider the following two studies examining the cumulative impacts of exporting domestically produced LNG:

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[1] Carib clarified this requested quantity in an email to DOE/FE dated July 18, 2016.

[2] Carib clarified its proposed mode of transport in an email to DOE/FE dated August 9, 2016.

[3] The Facilities include the following: The Trussville LNG facility (Trussville, Alabama), the Chattanooga LNG facility (Chattanooga, Tennessee), the Riverdale LNG facility (Riverdale, Georgia), the Cherokee LNG facility (Ball Ground, Georgia), and the Macon LNG facility (Macon, Georgia). Specifically, Carib states that it "will purchase" LNG from the Trussville and Chattanooga LNG facilities, and that, in the future, Pivotal "also would have the ability to source LNG" for sale to Carib from the other three Facilities, subject to any applicable regulatory approvals. App. at 4.

[4] In Appendix C to the Application, Carib provides a summary of the Master LNG Purchase and Sale Agreement between Carib and Pivotal, dated March 12, 2014. According to Carib, that Agreement provides Carib the right to purchase a firm or interruptible supply of LNG from the Facilities of up to 1.3 Bcf/d of natural gas for a term of 20 years.

- *Effect of Increased Levels of Liquefied Natural Gas on U.S. Energy Markets,* conducted by the U.S. Energy Information Administration upon DOE's request (2014 EIA LNG Export Study); [5] and
- *The Macroeconomic Impact of Increasing U.S. LNG Exports,* conducted jointly by the Center for Energy Studies at Rice University's Baker Institute for Public Policy and Oxford Economics, on behalf of DOE (2015 LNG Export Study).[6]

Additionally, DOE will consider the following environmental document:

- *Addendum to Environmental Review Documents Concerning Exports of Natural Gas From the United States,* 79 FR 48132 (Aug. 15, 2014).[7]

Parties that may oppose this Application should address these issues in their comments and/or protests, as well as other issues deemed relevant to the Application.

The National Environmental Policy Act (NEPA), 42 U.S.C. 4321 *et seq.,* requires DOE to give appropriate consideration to the environmental effects of its proposed decisions. No final decision will be issued in this proceeding until DOE has met its environmental responsibilities.

Public Comment Procedures

In response to this Notice, any person may file a protest, comments, or a motion to intervene or notice of intervention, as applicable. Due to the complexity of the issues raised by the Applicant, interested persons will be provided 60 days from the date of publication of this Notice in which to submit comments, protests, motions to intervene, or notices of intervention.

Any person wishing to become a party to the proceeding must file a motion to intervene or notice of intervention. The filing of comments or a protest with respect to the Application will not serve to make the commenter or protestant a party to the proceeding, although protests and comments received from persons who are not parties will be considered in determining the appropriate action to be taken on the Application. All protests, comments, motions to intervene, or notices of intervention must meet the requirements specified by the regulations in 10 CFR part 590.

Filings may be submitted using one of the following methods: (1) Emailing the filing to *fergas@hq.doe.gov,* with FE Docket No. 16–98–LNG in the title line; (2) mailing an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**; or (3) hand delivering an original and three paper copies of the filing to the Office of Regulation and International Engagement at the address listed in **ADDRESSES**. All filings must include a reference to FE Docket No. 16–98–LNG. PLEASE NOTE: If submitting a filing via email, please include all related documents and attachments (*e.g.,* exhibits) in the original email correspondence. Please do not include any active hyperlinks or password protection in any of the documents or attachments related to the filing. All electronic filings submitted to DOE must follow these guidelines to ensure that all documents are filed in a timely manner. Any hardcopy filing submitted greater in length than 50 pages must also include, at the time of the filing, a digital copy on disk of the entire submission.

A decisional record on the Application will be developed through responses to this notice by parties, including the parties' written comments and replies thereto. Additional procedures will be used as necessary to achieve a complete understanding of the facts and issues. If an additional procedure is scheduled, notice will be provided to all parties. If no party requests additional procedures, a final Opinion and Order may be issued based on the official record, including the Application and responses filed by parties pursuant to this notice, in accordance with 10 CFR 590.316.

The Application is available for inspection and copying in the Office of Regulation and International Engagement docket room, Room 3E–042, 1000 Independence Avenue SW., Washington, DC 20585. The docket room is open between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday, except Federal holidays.

The Application and any filed protests, motions to intervene or notice of interventions, and comments will also be available electronically by going to the following DOE/FE Web address: *http://www.fe.doe.gov/programs/gasregulation/index.html.*

Issued in Washington, DC, on August 11, 2016.

John A. Anderson,

Director, Office of Regulation and International Engagement, Office of Oil and Natural Gas.

[FR Doc. 2016–19618 Filed 8–16–16; 8:45 am]

BILLING CODE 6450–01–P

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[5] The 2014 EIA LNG Export Study, published on Oct. 29, 2014, is available at: *https://www.eia.gov/analysis/requests/fe/.*

[6] The 2015 LNG Export Study, dated Oct. 29, 2015, is available at: *http://energy.gov/sites/prod/files/2015/12/f27/20151113_macro_impact_of_lng_exports_0.pdf.*

[7] The Addendum and related documents are available at *http://energy.gov/fe/addendum-environmental-review-documents-concerning-exports-natural-gas-united-states.*

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket No. EL16–98–000]

Notice of Institution of Section 206 Proceeding and Refund Effective Date: Elwood Energy, LLC, Exelon Generation Company, LLC

On August 10, 2016, the Commission issued an order in Docket No. EL16–98–000, pursuant to section 206 of the Federal Power Act (FPA), 16 U.S.C. 824e (2012), instituting an investigation into the justness and reasonableness of the Elwood Facility's reactive power rates. *Elwood Energy, LLC, et al.,* 156 FERC ¶ 61,104 (2016).

The refund effective date in Docket No. EL16–98–000, established pursuant to section 206(b) of the FPA, will be the date of publication of this notice in the **Federal Register**.

Any interested person desiring to be heard in Docket No. EL16–98–000 must file a notice of intervention or motion to intervene, as appropriate, with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, in accordance with Rule 214 of the Commission's Rules of Practice and Procedure, 18 CFR 385.214, within 21 days of the date of issuance of the order.

Dated: August 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–19571 Filed 8–16–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Combined Notice of Filings #1

Take notice that the Commission received the following electric rate filings:

Docket Numbers: ER10–2398–004; ER10–2399–004; ER10–2423–007; ER10–2404–007; ER14–1933–004; ER10–2406–005; ER10–2408–004; ER10–2409–004; ER10–2410–004; ER10–2411–005; ER10–2412–005; ER10–2414–005; ER11–2935–006; ER13–1816–004.

Applicants: Blackstone Wind Farm, LLC, Blackstone Wind Farm II LLC, Flat Rock Windpower LLC, Flat Rock Windpower II LLC, Headwaters Wind Farm LLC, High Trail Wind Farm, LLC, Marble River, LLC, Meadow Lake Wind Farm II LLC, Meadow Lake Wind Farm III LLC, Meadow Lake Wind Farm IV LLC, Meadow Lake Wind Farm LLC, Old Trail Wind Farm, LLC, Paulding Wind Farm II LLC, Sustaining Power Solutions LLC.

Description: Notice of Non-Material Change in Status of Blackstone Wind Farm, LLC, et al.

Filed Date: 8/10/16.

Accession Number: 20160810–5257.

Comments Due: 5 p.m. ET 8/31/16.

Docket Numbers: ER10–2564–006; ER10–2600–006; ER10–2289–006.

Applicants: Tucson Electric Power Company, UNS Electric, Inc., UniSource Energy Development Company.

Description: Second Supplement to December 31, 2015 Triennial Market Power Update for the Southwest Region of the Fortis, Inc. subsidiaries, et al.

Filed Date: 8/11/16.

Accession Number: 20160811–5192.

Comments Due: 5 p.m. ET 10/11/16.

Docket Numbers: ER16–736–004.

Applicants: PJM Interconnection, L.L.C.

Description: Compliance filing: Compliance filing to July 11, 2016 order in Docket Nos. ER16–736 and EL16–96 to be effective 4/14/2016.

Filed Date: 8/10/16.

Accession Number: 20160810–5207.

Comments Due: 5 p.m. ET 8/31/16.

Docket Numbers: ER16–1827–001.

Applicants: GenOn Energy Management, LLC.

Description: Tariff Amendment: Response to Deficiency Letter to be effective 6/1/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5090.

Comments Due: 5 p.m. ET 9/1/16.

Docket Numbers: ER16–2400–000.

Applicants: PacifiCorp.

Description: Compliance filing: OATT Revised Attachments N & O (Orders 827 & 828) to be effective 10/14/2016.

Filed Date: 8/10/16.

Accession Number: 20160810–5208.

Comments Due: 5 p.m. ET 8/31/16.

Docket Numbers: ER16–2401–000.

Applicants: PJM Interconnection, LLC.

Description: Compliance filing: Compliance filing to July 11, 2016 order in Docket Nos. ER16–736 and EL16–96 to be effective 10/10/2016.

Filed Date: 8/10/16.

Accession Number: 20160810–5217.

Comments Due: 5 p.m. ET 8/31/16.

Docket Numbers: ER16–2402–000.

Applicants: UGI Utilities Inc.

Description: Market-Based Triennial Review Filing: Triennial Market Power Analyses and Change in Status to be effective 10/10/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5051.

Comments Due: 5 p.m. ET 10/11/16.

Docket Numbers: ER16–2403–000.

Applicants: UGI Development Company.

Description: Market-Based Triennial Review Filing: Triennial Market Power Analyses and Change in Status to be effective 10/10/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5054.

Comments Due: 5 p.m. ET 10/11/16.

Docket Numbers: ER16–2404–000.

Applicants: UGI Energy Services, Inc.

Description: Market-Based Triennial Review Filing: Triennial Market Power Analyses and Change in Status to be effective 10/10/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5056.

Comments Due: 5 p.m. ET 10/11/16.

Docket Numbers: ER16–2405–000.

Applicants: NRG Rockford II LLC.

Description: Section 205(d) Rate Filing: Notice of Succession and Revisions to Market-Based Rate Tariff to be effective 7/14/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5123.

Comments Due: 5 p.m. ET 9/1/16.

Docket Numbers: ER16–2406–000.

Applicants: NRG Rockford LLC.

Description: § 205(d) Rate Filing: Notice of Succession and Revisions to Market-Based Rate Tariff to be effective 7/13/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5124.

Comments Due: 5 p.m. ET 9/1/16.

Docket Numbers: ER16–2407–000.

Applicants: Consumers Energy Company, Midcontinent Independent System Operator, Inc.

Description: Section 205(d) Rate Filing: 2016–08–11_SA 2913 WPSC-Consumers Amended FCA (J392) to be effective 4/8/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5141.

Comments Due: 5 p.m. ET 9/1/16.

Docket Numbers: ER16–2408–000.

Applicants: Midcontinent Independent System Operator, Inc.

Description: Notice of Termination of Large Generator Interconnection Agreement designated Project No. G686, Original Service Agreement No. 1882 of Midcontinent Independent System Operator, Inc.

Filed Date: 8/11/16.

Accession Number: 20160811–5152.

Comments Due: 5 p.m. ET 9/1/16.

Docket Numbers: ER16–2409–000.

Applicants: Aurora Generation, LLC.

Description: Section 205(d) Rate Filing: Notice of Succession and Revised Rate Schedule to be effective 7/12/2016.

Filed Date: 8/11/16.

Accession Number: 20160811–5191.

Comments Due: 5 p.m. ET 9/1/16.

Take notice that the Commission received the following public utility holding company filings:

Docket Numbers: PH16–12–000.

Applicants: New Jersey Resources Corporation.

Description: New Jersey Resources Corporation submits FERC 65–A Notice of Non Material Change in Facts of Exemption Notification.

Filed Date: 8/10/16.

Accession Number: 20160810–5224.

Comments Due: 5 p.m. ET 8/31/16.

The filings are accessible in the Commission's eLibrary system by clicking on the links or querying the docket number.

Any person desiring to intervene or protest in any of the above proceedings must file in accordance with Rules 211 and 214 of the Commission's Regulations (18 CFR 385.211 and 385.214) on or before 5 p.m. Eastern time on the specified comment date. Protests may be considered, but intervention is necessary to become a party to the proceeding.

eFiling is encouraged. More detailed information relating to filing requirements, interventions, protests, service, and qualifying facilities filings can be found at: *http://www.ferc.gov/docs-filing/efiling/filing-req.pdf.* For other information, call (866) 208–3676 (toll free). For TTY, call (202) 502–8659.

Dated: August 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–19568 Filed 8–16–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

Notice of FERC Staff Attendance at the Entergy Regional State Committee Meeting

The Federal Energy Regulatory Commission (Commission) hereby gives notice that members of its staff may attend the meeting noted below. Their attendance is part of the Commission's ongoing outreach efforts.

Entergy Regional State Committee

August 19, 2016 (9:30 a.m.–12:30 p.m. Central)

This meeting will be held at the Capital Hotel, 111 West Markham St., Little Rock, AR 72201.

The discussions may address matters at issue in the following proceedings:

Docket No. EL95–33—*Louisiana Public Service Commission et al.* v. *Entergy Corp. et al.*

Docket No. EL00–66—*Louisiana Public Service Commission, et al.* v. *Entergy Corp., et al.*

Docket No. EL01–88—*Louisiana Public Service Commission* v. *Entergy Services, Inc.*

Docket No. EL09–61—*Louisiana Public Service Commission* v. *Entergy Services, Inc.*

Docket No. EL10–65—*Louisiana Public Service Commission* v. *Entergy Services, Inc.*

Docket No. EL14–19—Midcontinent Independent System Operator and Entergy Services, Inc.

Docket No. EL16–7—*City of Osceola, Arkansas* v. *Entergy Arkansas, Inc.*

Docket No. ER10–1350—*Entergy Arkansas, Inc.*

Docket No. ER13–432—*Entergy Arkansas, Inc.*

Docket No. ER13–948—*Entergy Arkansas, Inc.*

Docket No. ER13–1195—*Entergy Arkansas, Inc.*

Docket No. ER13–1508—*Entergy Arkansas, Inc.*

Docket No. ER13–1509—*Entergy Gulf States Louisiana, L.L.C.*

Docket No. ER13–1510—*Entergy Louisiana, LLC.*

Docket No. ER13–1511—*Entergy Mississippi, Inc.*

Docket No. ER13–1512—*Entergy New Orleans, Inc.*

Docket No. ER13–1513—*Entergy Texas, Inc.*

Docket No. ER14–649—*Midcontinent Independent System Operator, Inc.*

Docket No. ER14–693—*Entergy Services, Inc.*

Docket No. ER14–694—*Entergy Services, Inc.*

Docket No. ER14–695—*Entergy Services, Inc.*

Docket No. ER14–696—*Entergy Services, Inc.*

Docket No. ER14–697—*Entergy Services, Inc.*

Docket No. ER14–699—*Entergy Services, Inc.*

Docket No. ER14–700—*Entergy Services, Inc.*

Docket No. ER14–701—*Entergy Services, Inc.*

Docket No. ER14–702—*Entergy Arkansas, Inc.*

Docket No. ER14–703—*Entergy Services, Inc.*

Docket No. ER14–704—*Entergy Services, Inc.*

Docket No. ER14–1640—*Entergy Gulf States Louisiana, L.L.C*

Docket No. ER14–1641—*Entergy Louisiana, LLC.*

Docket No. ER14–1642—*Entergy Mississippi, Inc.*

Docket No. ER14–1643—*Entergy New Orleans, Inc.*

Docket No. ER14–1644—*Entergy Texas, Inc.*

Docket No. ER14–2850—*Southwest Power Pool, Inc.*

Docket No. ER14–2851—*Southwest Power Pool, Inc.*

Docket No. ER15–1436—*Entergy Gulf States Louisiana, L.L.C.*

Docket No. ER15–1453—*Entergy Arkansas, Inc.*

Docket No. ER15–1826—*Entergy Services, Inc.*

Docket No. ER16–227—*Entergy Arkansas, Inc.*

Docket No. ER16–1087—*Entergy New Orleans, Inc.*

Docket No. ER16–1251—*Entergy Louisiana, LLC.*

Docket No. ER16–1316—*Entergy Services, Inc.*

Docket No. ER16–1528—*Entergy Arkansas, Inc.*

Docket No. ER16–1806—*Entergy Services, Inc.*

Docket No. ER16–1965—*Entergy Louisiana, LLC.*

Docket No. ER16–2034—*Entergy Louisiana, LLC.*

Docket No. ER16–2124—*Entergy New Orleans, Inc.*

Docket No. ER16–2125—*Entergy Louisiana, LLC.*

Docket No. ER16–2199—*Entergy Arkansas, Inc.*

Docket No. ER16–2200—*Midcontinent Independent System Operator, Inc.*

These meetings are open to the public.

For more information, contact Patrick Clarey, Office of Energy Market Regulation, Federal Energy Regulatory Commission at (317) 249–5937 or *patrick.clarey@ferc.gov.*

Dated: August 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–19572 Filed 8–16–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–487–000, PF15–32–000]

Northern Natural Gas Company; Notice of Application

Take notice that on July 29, 2016, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124–1000, filed in Docket No. CP16–487–000 an application pursuant to section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's Regulations, requesting authorization to construct and operate 7.86-mile-long 20-inch-diameter pipeline with appurtenances located in Dakota County, Minnesota (Cedar Station Upgrade Project). Northern also requests a predetermination of rolled-in rate treatment, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Michael T. Loeffler, Senior Director, Certificates and External Affairs for Northern, 1111 South 103rd Street, Omaha, Nebraska 68124, or by calling (402) 398–7103.

Specifically, Northern designed the Cedar Station Upgrade Project to increase the delivery pressure at Northern's existing Cedar Station located in Eagan, Minnesota, in accordance with a contractual obligation for Northern States Power Company (NSP–MN). The proposed pipeline will originate at Northern's existing Rosemount Junction facility in Rosemount, Minnesota and extend to its existing Cedar Station. Northern states that due to mainline constraints upstream of the branch line, the proposed project is not expected to generate incremental capacity that can be sold. The requested order date and proposed in-service date are March 17, 2017 and November 1, 2017 respectively. The project cost is estimated at $49,865,629.

On October 9, 2015, the Commission staff granted Northern's request to utilize the Pre-Filing Process and assigned Docket No. PF15–32–000 to staff activities involved in the above referenced project. Now, as of the filing of the July 29, 2016 application, the Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–487–000, as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit original and five copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5:00 p.m. Eastern Time on September 1, 2016.

Dated: August 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–19570 Filed 8–16–16; 8:45 am]

BILLING CODE 6717–01–P

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

[Docket Nos. CP16–486–000, PF16–3–000]

Notice of Application Millennium Pipeline Company, LLC

Take notice that on July 29, 2016, Millennium Pipeline Company (Millennium), One Blue Hill Plaza, Pearl River, New York 10965, filed in Docket No. CP16–486–000 an application pursuant to section 7(c) of the Natural Gas Act (NGA), and Part 157 of the Commission's Regulations, requesting a certificate of public convenience and necessity authorizing their Eastern System Upgrade Project. This project will provide an additional 223 million cubic feet per day (MMcf/d) of firm transportation capacity from Millennium's Corning Compressor Station (CS) to an existing interconnection with Algonquin Gas Transmission, LLC located in Ramapo, New York, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

The filing may also be viewed on the web at *http://www.ferc.gov* using the "eLibrary" link. Enter the docket number excluding the last three digits in the docket number field to access the document. For assistance, please contact FERC Online Support at *FERCOnlineSupport@ferc.gov* or toll free at (866) 208–3676, or TTY, contact (202) 502–8659.

Any questions concerning this application may be directed to Georgia Carter, Vice President and General Counsel, Millennium Pipeline Company, LLC, 109 North Post Oak Lane, Suite 210, Houston, TX 77024, by calling 804–921–1408, or emailing *carter@millenniumpipeline.com.*

Specifically, Millennium proposes to construct, operate, and maintain (1) Approximately 7.8-miles of 30- and 36-inch-diameter pipeline loop in Orange County, New York; (2) a new 22,400 horsepower (HP) compressor station in Sullivan County, New York; (3) additional 22,400 HP at the existing Hancock Compressor Station in Delaware County, New York; (4) modifications to the existing Ramapo Meter and Regulator Station in Rockland County, New York; (5) modifications to the Wagoner Interconnect in Orange County, New York; (6) additional pipeline appurtenant facilities at the existing Huguenot and Westtown Meter and Regulating Stations in Orange County, New York; and (7) an alternate interconnect to the 16-inch-diameter Valley Lateral at milepost 7.6 of the Project.

Millennium states that 202.5 MMcf/d of project capacity is committed under precedent agreements with local distribution companies and municipalities. Millennium requests that the Commission issue the requested authorizations by July 31, 2017, in order to allow Millennium sufficient time to meet a targeted in-service date in September 2018. Millennium proposes to charge negotiated rates to its project shippers and existing Rate Schedule FT–1 rates for service on the expansion capacity created by the project. The cost of the project is $275,000,000.

On February 5, 2016, the Commission staff granted Millennium's request to utilize the Pre-Filing Process and assigned Docket No. PF16–3–000 to staff activities involved in the above referenced project. Now, as of the filing of the July 29, 2016 application, the Pre-Filing Process for this project has ended. From this time forward, this proceeding will be conducted in Docket No. CP16–486–000, as noted in the caption of this Notice.

Pursuant to section 157.9 of the Commission's rules, 18 CFR 157.9, within 90 days of this Notice the

Commission staff will either: Complete its environmental assessment (EA) and place it into the Commission's public record (eLibrary) for this proceeding; or issue a Notice of Schedule for Environmental Review. If a Notice of Schedule for Environmental Review is issued, it will indicate, among other milestones, the anticipated date for the Commission staff's issuance of the EA for this proposal. The filing of the EA in the Commission's public record for this proceeding or the issuance of a Notice of Schedule for Environmental Review will serve to notify federal and state agencies of the timing for the completion of all necessary reviews, and the subsequent need to complete all federal authorizations within 90 days of the date of issuance of the Commission staff's EA.

There are two ways to become involved in the Commission's review of this project. First, any person wishing to obtain legal status by becoming a party to the proceedings for this project should, on or before the comment date stated below, file with the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426, a motion to intervene in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the NGA (18 CFR 157.10). A person obtaining party status will be placed on the service list maintained by the Secretary of the Commission and will receive copies of all documents filed by the applicant and by all other parties. A party must submit five copies of filings made with the Commission and must mail a copy to the applicant and to every other party in the proceeding. Only parties to the proceeding can ask for court review of Commission orders in the proceeding.

However, a person does not have to intervene in order to have comments considered. The second way to participate is by filing with the Secretary of the Commission, as soon as possible, an original and two copies of comments in support of or in opposition to this project. The Commission will consider these comments in determining the appropriate action to be taken, but the filing of a comment alone will not serve to make the filer a party to the proceeding. The Commission's rules require that persons filing comments in opposition to the project provide copies of their protests only to the party or parties directly involved in the protest.

Persons who wish to comment only on the environmental review of this project should submit an original and two copies of their comments to the Secretary of the Commission. Environmental commentors will be placed on the Commission's environmental mailing list, will receive copies of the environmental documents, and will be notified of meetings associated with the Commission's environmental review process. Environmental commentors will not be required to serve copies of filed documents on all other parties. However, the non-party commentors will not receive copies of all documents filed by other parties or issued by the Commission (except for the mailing of environmental documents issued by the Commission) and will not have the right to seek court review of the Commission's final order.

The Commission strongly encourages electronic filings of comments, protests and interventions in lieu of paper using the "eFiling" link at *http://www.ferc.gov.* Persons unable to file electronically should submit original and five copies of the protest or intervention to the Federal Energy Regulatory Commission, 888 First Street NE., Washington, DC 20426.

Comment Date: 5 p.m. Eastern Time on September 1, 2016.

Dated: August 11, 2016.

Nathaniel J. Davis, Sr.,

Deputy Secretary.

[FR Doc. 2016–19569 Filed 8–16–16; 8:45 am]

BILLING CODE 6717–01–P

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9950–99–OGC; EPA–HQ–OGC–2016–0364]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Supplemental notice of proposed consent decree; request for public comment.

SUMMARY: Supplemental notice is hereby given for the Wyoming portions of a proposed consent decree to address a lawsuit filed by the Sierra Club ("Plaintiff") in the United States District Court for the Northern District of California: *Sierra Club* v. *Gina McCarthy,* No. 3:15–cv–04328–JD (N.D. Cal.). On September 22, 2015, Plaintiffs filed this matter against Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency ("EPA"). On February 9, 2016, Plaintiff filed a first amended complaint alleging that, with respect to the 2008 ozone national ambient air quality standards ("NAAQS"), EPA has failed to perform non-discretionary duties to take final action on portions of the state implementation plan ("SIP") submission from Wyoming intended to address various interstate transport requirements. The proposed consent decree would establish a deadline for EPA to take certain specified actions.

DATES: Written comments on the Wyoming portions of the proposed consent decree must be received by September 1, 2016.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2016–0364, online at *www.regulations.gov.* For comments submitted at *Regulations.gov,* follow the online instructions for submitting comments. Once submitted, comments cannot be edited or removed from *Regulations.gov.* The EPA may publish any comment received to its public docket. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Multimedia submissions (audio, video, etc.) must be accompanied by a written comment. The written comment is considered the official comment and should include discussion of all points you wish to make. The EPA will generally not consider comments or comment contents located outside of the primary submission (*i.e.* on the web, cloud, or other file sharing system). For additional submission methods, please contact the person identified in the "For Further Information Contact" section. For the full EPA public comment policy, information about CBI or multimedia submissions, and general guidance on making effective comments, please visit *http://www2.epa.gov/dockets/commenting-epa-dockets.*

FOR FURTHER INFORMATION CONTACT: Zachary Pilchen, Air and Radiation Law Office, Office of General Counsel, U.S. Environmental Protection Agency; telephone: (202) 564–2812; fax number (202) 564–5603; email address: *pilchen.zach@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree and This Supplemental Notice With Regard to Wyoming

This proposed consent decree would resolve a lawsuit filed by Plaintiffs seeking to compel the Administrator to take action under Clean Air Act ("CAA") section 110(k)(2)–(4). As relevant to this supplemental notice, Plaintiffs allege that the Administrator has failed to perform a non-discretionary duty to take final action on portions of Wyoming's SIP submission intended to address the requirements of 42 U.S.C. 7410(a)(2)(D)(i) for the 2008 ozone NAAQS.

EPA previously published notice of this proposed consent decree on June 29, 2016.[1] The "Summary" section of that notice listed a number of states with SIP submissions relevant to the proposed consent decree and notice, including Wyoming. The proposed consent decree itself—to which the notice directed readers for more details—included the specific claims and dates relevant to Wyoming. The Wyoming Department of Environmental Quality ("WDEQ") submitted comments on the proposed consent decree, including with respect to those proposed consent decree dates, which WDEQ accurately characterized as "Proposed Consent Decree Deadlines Applicable to Wyoming's Submittal."[2]

A separate part of that June 29, 2016 notice, however, included a scrivener's error. In the "Supplementary Information" section, the notice briefly summarized (in alphabetical order by state) the allegations regarding SIP submissions. As WDEQ noted in its comment letter, despite Wyoming's inclusion in the "Summary" section of the notice, the "Supplementary Information" section did not list Wyoming, and instead listed Wisconsin as both of the two final states.[3] The second reference to Wisconsin was a scrivener's error that should have referred to Wyoming, as WDEQ correctly concluded in its comments on the proposed consent decree deadlines for Wyoming.

WDEQ commented, however, that as a result of this error the notice was "unclear" about "what allegation details" apply to Wyoming.[4] CAA section 113(g) requires notice of a proposed consent decree; supplementary information about the allegations is not required. However, as a courtesy and out of an abundance of caution, for a period of fifteen (15) days following the date of publication of this supplemental notice, the Agency will accept written comments relating solely to the Wyoming portions of the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the Wyoming portions of the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the proposed consent decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2016–0364) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use the *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select "search."

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked "late." EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: August 10, 2016.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2016–19638 Filed 8–16–16; 8:45 am]

BILLING CODE 6560–50–P

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[1] 81 FR 42351 (June 29, 2016).

[2] *See* Comment of WDEQ at 1, Docket No. EPA–HQ–OGC–2016–0364–0004.

[3] *See* 81 FR at 42351, col. 3.

[4] Comment of WDEQ at 1.

ENVIRONMENTAL PROTECTION AGENCY

[FRL–9951–00–OGC; EPA–HQ–OGC–2016–0480]

Proposed Consent Decree, Clean Air Act Citizen Suit

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed consent decree; request for public comment.

SUMMARY: In accordance with section 113(g) of the Clean Air Act, as amended (''CAA'' or the ''Act''), 42 U.S.C. 7413(g), notice is hereby given of a proposed consent decree to address a lawsuit filed by Concerned Citizens of Seneca County, Inc. and Dixie D. Lemmon, (collectively ''Plaintiffs''): *Concerned Citizens of Seneca County, Inc.* v. *McCarthy,* No. 6:16–cv–06196 (W.D.N.Y.). On March 25, 2016, Plaintiffs filed the complaint in this case alleging that Gina McCarthy, in her official capacity as Administrator of the United States Environmental Protection Agency (''EPA''), failed to perform a non-discretionary duty to grant or deny within 60 days a petition submitted by Plaintiffs. In their petition, Plaintiffs requested that EPA object to a CAA Title V permit issued by the New York State Department of Environmental Conservation to the Seneca County Landfill Gas-to-Energy Facility, for purposes of operating a landfill gas-to-energy facility in Seneca Falls, New York. The proposed consent decree would establish a deadline for EPA to respond to this petition.

DATES: Written comments on the proposed consent decree must be received by September 16, 2016.

ADDRESSES: Submit your comments, identified by Docket ID number EPA–HQ–OGC–2016–0480, online at *www.regulations.gov* (EPA's preferred method); by email to *oei.docket@epa.gov;* by mail to EPA Docket Center, Environmental Protection Agency, Mailcode: 2822T, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; or by hand delivery or courier to EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave. NW., Washington, DC, between 8:30 a.m. and 4:30 p.m. Monday through Friday, excluding legal holidays. Comments on a disk or CD–ROM should be formatted in Word or ASCII file, avoiding the use of special characters and any form of encryption, and may be mailed to the mailing address above.

FOR FURTHER INFORMATION CONTACT: Zachary Pilchen, Air and Radiation Law Office (2344A), Office of General Counsel, U.S. Environmental Protection Agency, 1200 Pennsylvania Ave. NW. Washington, DC 20460; telephone: (202) 564–2812; fax number (202) 564–5603; email address: *pilchen.zach@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Additional Information About the Proposed Consent Decree

This proposed consent decree would resolve a lawsuit filed by Plaintiffs seeking to compel the Administrator to take actions under CAA section 505(b)(2). Under the terms of the proposed consent decree, EPA would agree to sign a response to the petition by December 9, 2016. The proposed consent decree also provides for the possibility that certain circumstances could delay compliance with the December 9, 2016 deadline, and provides a framework for extending that deadline. In addition, the proposed consent decree also establishes a framework for resolving any request for costs of litigation, including attorney fees, and provides that after such resolution the proposed consent decree will be terminated and the case dismissed.

For a period of thirty (30) days following the date of publication of this notice, the Agency will accept written comments relating to the proposed consent decree from persons who are not named as parties or intervenors to the litigation in question. EPA or the Department of Justice may withdraw or withhold consent to the proposed consent decree if the comments disclose facts or considerations that indicate that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act. Unless EPA or the Department of Justice determines that consent to this consent decree should be withdrawn or withheld, the terms of the consent decree will be affirmed.

II. Additional Information About Commenting on the Proposed Consent Decree

A. How can I get a copy of the proposed consent decree?

The official public docket for this action (identified by Docket ID No. EPA–HQ–OGC–2016–0480) contains a copy of the proposed consent decree. The official public docket is available for public viewing at the Office of Environmental Information (OEI) Docket in the EPA Docket Center, EPA West, Room 3334, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566–1744, and the telephone number for the OEI Docket is (202) 566–1752.

An electronic version of the public docket is available through *www.regulations.gov.* You may use the *www.regulations.gov* to submit or view public comments, access the index listing of the contents of the official public docket, and access those documents in the public docket that are available electronically. Once in the system, key in the appropriate docket identification number then select ''search.''

It is important to note that EPA's policy is that public comments, whether submitted electronically or in paper, will be made available for public viewing online at *www.regulations.gov* without change, unless the comment contains copyrighted material, CBI, or other information whose disclosure is restricted by statute. Information claimed as CBI and other information whose disclosure is restricted by statute is not included in the official public docket or in the electronic public docket. EPA's policy is that copyrighted material, including copyrighted material contained in a public comment, will not be placed in EPA's electronic public docket but will be available only in printed, paper form in the official public docket. Although not all docket materials may be available electronically, you may still access any of the publicly available docket materials through the EPA Docket Center.

B. How and to whom do I submit comments?

You may submit comments as provided in the **ADDRESSES** section. Please ensure that your comments are submitted within the specified comment period. Comments received after the close of the comment period will be marked ''late.'' EPA is not required to consider these late comments.

If you submit an electronic comment, EPA recommends that you include your name, mailing address, and an email address or other contact information in the body of your comment and with any disk or CD ROM you submit. This ensures that you can be identified as the submitter of the comment and allows EPA to contact you in case EPA cannot read your comment due to technical difficulties or needs further information on the substance of your comment. Any identifying or contact information provided in the body of a comment will be included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket. If EPA cannot read your comment due to technical difficulties and cannot contact you for clarification, EPA may not be able to consider your comment.

Use of the *www.regulations.gov* Web site to submit comments to EPA electronically is EPA's preferred method for receiving comments. The electronic public docket system is an "anonymous access" system, which means EPA will not know your identity, email address, or other contact information unless you provide it in the body of your comment. In contrast to EPA's electronic public docket, EPA's electronic mail (email) system is not an "anonymous access" system. If you send an email comment directly to the Docket without going through *www.regulations.gov,* your email address is automatically captured and included as part of the comment that is placed in the official public docket, and made available in EPA's electronic public docket.

Dated: August 10, 2016.

Lorie J. Schmidt,

Associate General Counsel.

[FR Doc. 2016–19639 Filed 8–16–16; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[EPA–HQ–OPP–2016–0310; FRL–9950–76]

Plant-Incorporated Protectants: Proposed Modifications of Registration Procedures for Plant-Incorporated Protectants in Breeding Line Intermediates; Notice of Availability; Extension of Comment Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice; extension of comment period.

SUMMARY: EPA issued a notice in the **Federal Register** of June 30, 2016, concerning the availability for public comment of a White Paper describing how the Agency is proposing to modify its current approach to plant-incorporated protectants in breeding line intermediates under section 3 of the Federal Insecticide, Fungicide and Rodenticide Act. This document extends the comment period for 45 days, from August 15, 2016 to September 29, 2016. Stakeholders have expressed a desire to comment on EPA's proposal and have requested additional time to review the proposal and respond.

DATES: Comments, identified by docket identification (ID) number EPA–HQ–OPP–2016–0310, must be received on or before September 29, 2016.

ADDRESSES: Follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of June 30, 2016 (81 FR 42704) (FRL–9947–25).

FOR FURTHER INFORMATION CONTACT: Robert McNally, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460–0001; main telephone number: (703) 305–7090; email address: *BPPDFRNotices@epa.gov.*

SUPPLEMENTARY INFORMATION:

This document extends the public comment period established in the **Federal Register** document of June 30, 2016 (81 FR 42704) (FRL–9947–25). In that document, EPA makes available for public comment a White Paper describing how the Agency is proposing to modify its current approach to plant-incorporated protectants in breeding line intermediates under Section 3, Registration of Pesticides, of the Federal Insecticide, Fungicide and Rodenticide Act. EPA is hereby extending the comment period, which was set to end on August 15, 2016, to September 29, 2016.

To submit comments, or access the docket, please follow the detailed instructions provided under **ADDRESSES** in the **Federal Register** document of June 30, 2016. If you have questions, consult the person listed under **FOR FURTHER INFORMATION CONTACT.**

Authority: 7 U.S.C. 136 *et seq.*

Dated: August 11, 2016.

Robert C. McNally,

Director, Biopesticides and Pollution Prevention Division, Office of Pesticide Programs.

[FR Doc. 2016–19646 Filed 8–16–16; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL MARITIME COMMISSION

[Docket No. 16–16]

MAVL Capital, Inc., IAM & AL Group Inc., and Maxim Ostrovskiy V. Marine Transport Logistics, Inc. and Dimitry Alper: Notice of Filing of Complaint and Assignment

Notice is given that a Complaint has been filed with the Federal Maritime Commission (Commission) by MAVL Capital, Inc. ("MAVL"), IAM & AL GROUP INC. ("IAM"), and Maxim Ostrovskiy, hereinafter "Complainants," against Marine Transport Logistics, Inc. ("MTL") and Dimitry Alper, hereinafter "Respondents." Complainants allege that Respondents are a non-vessel-operating common carrier ("NVOCC") licensed by the Commission and its director of operations, "engaged in the business of exporting used cars, motorcycles, and other cargo . . . from the United States to ports abroad." Complainants allege that they had a business relationship with Respondents, having hired Respondents to ship Complainants' vehicles.

Complainants allege that Respondents violated provisions of the Shipping Act of 1984, including 46 U.S.C. 41102, 41101 and 46 CFR part 515, by:

> "i. Failing to establish, observe, and enforce just and reasonable regulations and practices relating to or connected with receiving, handling, storing, or delivering property;
>
> ii. Unreasonably refusing to deal or negotiate;
>
> iii. Retaliating against Complainants because the Complainants had patronized another carrier;
>
> iv. Knowingly misdelivering Complainants' cargo; and
>
> v. Converting Complainants' cargo under the false premise of having exercised a maritime lien."

Complainants allege damages "in excess of $180,000" and request the following relief:

> "(1) Respondents be required to answer the charges herein; (2) that after due hearing, an order be made commanding said respondent to pay to Complainants by way of reparations for the unlawful conduct hereinabove described, the sums described herein, with interest and attorney's fees, costs and expenses, or such other sum as the Commission may determine to be proper as an award of reparation; (3) that the Commission issue an Order holding that the respondents Dimitry Alper individually, and Marine Transport Logistics, Inc. violated the Shipping Act of 1984; and (4) that the Commission issue such other and further order or orders as the Commission determines to be just and proper."

The full text of the complaint can be found in the Commission's Electronic Reading Room at *www.fmc.gov/16-16.*

This proceeding has been assigned to the Office of Administrative Law Judges. The initial decision of the presiding officer in this proceeding shall be issued by August 11, 2017 and the final decision of the Commission shall be issued by February 26, 2018.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–19653 Filed 8–16–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL MARITIME COMMISSION

Notice of Agreements Filed

The Commission hereby gives notice of the filing of the following agreement under the Shipping Act of 1984. Interested parties may submit comments on the agreements to the Secretary, Federal Maritime Commission, Washington, DC 20573, within twelve days of the date this notice appears in the **Federal Register**. Copies of the agreements are available through the Commission's Web site (*www.fmc.gov*) or by contacting the Office of Agreements at (202)-523–5793 or *tradeanalysis@fmc.gov.*

Agreement No.: 011223–053.

Title: Transpacific Stabilization Agreement.

Parties: American President Lines, Ltd. and APL Co. PTE Ltd.; (operating as a single carrier); Maersk Line A/S; CMA CGM, S.A.; COSCO Container Lines Company Ltd; Evergreen Line Joint Service Agreement; Hanjin Shipping Co., Ltd.; Hapag-Lloyd AG; Hyundai Merchant Marine Co., Ltd.; Mediterranean Shipping Company; Nippon Yusen Kaisha; Orient Overseas Container Line Limited; Yangming Marine Transport Corp.; and Zim Integrated Shipping Services, Ltd.

Filing Party: David F. Smith, Esq.; Cozen O'Conner; 1200 Nineteenth Street NW.; Washington, DC 20036.

Synopsis: The amendment removes Kawasaki Kisen Kaisha Ltd. as a party to the Agreement effective August 19, 2016.

By Order of the Federal Maritime Commission.

Dated: August 12, 2016.

Rachel E. Dickon,

Assistant Secretary.

[FR Doc. 2016–19633 Filed 8–16–16; 8:45 am]

BILLING CODE 6731–AA–P

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The applications will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than September 12, 2016.

A. Federal Reserve Bank of Richmond (Adam M. Drimer, Assistant Vice President) 701 East Byrd Street, Richmond, Virginia 23261–4528. Comments can also be sent electronically to or *Comments.applications@rich.frb.org:*

1. *First Bancorp, Southern Pines, North Carolina*; to acquire 100 percent of the voting securities of Carolina Bank Holdings, Inc., Greensboro, North Carolina, and thereby indirectly acquire Carolina Bank, Greensboro, North Carolina.

Board of Governors of the Federal Reserve System, August 12, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–19620 Filed 8–16–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Agency Information Collection Activities: Announcement of Board Approval Under Delegated Authority and Submission to OMB

AGENCY: Board of Governors of the Federal Reserve System.

SUMMARY: Notice is hereby given of the final approval of a proposed information collection by the Board of Governors of the Federal Reserve System (Board) under OMB delegated authority, as per 5 CFR 1320.16 (OMB Regulations on Controlling Paperwork Burdens on the Public). Board-approved collections of information are incorporated into the official OMB inventory of currently approved collections of information. Copies of the Paperwork Reduction Act Submission, supporting statements and approved collection of information instrument(s) are placed into OMB's public docket files. The Federal Reserve may not conduct or sponsor, and the respondent is not required to respond to, an information collection that has been extended, revised, or implemented on or after October 1, 1995, unless it displays a currently valid OMB control number.

FOR FURTHER INFORMATION CONTACT: Federal Reserve Board Clearance Officer—Nuha Elmaghrabi—Office of the Chief Data Officer, Board of Governors of the Federal Reserve System, Washington, DC 20551, (202) 452–3829. Telecommunications Device for the Deaf (TDD) users may contact (202) 263–4869, Board of Governors of the Federal Reserve System, Washington, DC 20551.

OMB Desk Officer—Shagufta Ahmed—Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Room 10235, 725 17th Street NW., Washington, DC 20503.

Final approval under OMB delegated authority of the extension for three years, with revision, of the following reports:

1. *Report title:* Savings and Loan Holding Company Registration Statement.

Agency form number: FR LL–10(b).

OMB control number: 7100–0337.

Frequency: As needed.

Respondents: Newly Formed Savings and Loan Holding Companies.

Estimated number of respondents: 3.

Estimated average hours per response: 8 hours.

Estimated annual burden hours: 24.

General Description of Report: The FR LL–10(b) includes information on the financial condition, ownership, operations, management, and intercompany relationships of the SLHC and its subsidiaries.

Federal Reserve staff review the FR LL–10(b) to assess the adequacy of responses to items, disclosure of pertinent facts, and completeness in all material respects. This includes information concerning the date of consummation of transactions and the number of shares acquired.

Legal authorization and confidentiality: The Boards' Legal Division has determined that FR LL–10(b) is authorized by section 10(b)(1) of the HOLA and Regulation LL, 12 CFR 238.4(c). Section 10(b) of the Home Owners' Loan Act, as amended (HOLA), 12 U.S.C. 1467a(b)(1), provides that each SLHC is required to register with the Federal Reserve within 90 days of becoming an SLHC on forms prescribed by the Board that contain such information as the Board may deem necessary or appropriate. The Board is therefore authorized to collect information on this form pursuant to section 10(b) of HOLA. The obligation to respond is mandatory, as described in the previous paragraph. Information contained in the FR LL–10(b) is not considered confidential. If an SLHC wishes to claim confidential treatment for any information submitted on or with the form, it would need to describe the circumstances and provide a justification for the withholding of the information consistent with the Freedom of Information Act, 5 U.S.C. 552.

Current Actions: On June 1, 2016, the Federal Reserve published a notice in the **Federal Register** (81 FR 35015) requesting public comment for 60 days on the extension of the FR LL–10(b). The comment period for this notice expired on August 1, 2016. The Federal Reserve did not receive any comments. The revisions will be implemented as proposed.

2. Report title: Notice of Proposed Declaration of Dividend.

Agency form number: FR 1583.

OMB control number: 7100–0339.

Frequency: As needed.

Respondents: Savings and Loan Holding Companies.

Estimated number of respondents: 133.

Estimated average hours per response: 16.5 minutes.

Estimated annual burden hours: 73.

General Description of Report: Savings association subsidiaries of SLHCs provide prior notice of a dividend by filing form FR 1583 that requires information on (1) the date of the filing, (2) the nature and amount of the proposed dividend declaration, and (3) the names and signatures of the executive officer and secretary of the savings association that have provided the notice. The savings association subsidiary must file this prior notice at least 30 days before the proposed declaration of a dividend by its board of directors. This notice may include a schedule proposing dividends of over a specified period, up to 12 months. The statute also provides that the 30-day period commences on the date of receipt of the complete record of the notice by the Federal Reserve. The Federal Reserve Board may request additional information or may impose conditions for the dividend and may determine that such dividend does not comply with the requirements of 12 CFR part 238, subpart K.

Legal authorization and confidentiality: The Board's Legal Division determined that FR 1583 is authorized by section 10(f) of the Home Owners' Loan Act (HOLA) and section 238.103 of Regulation LL (12 CFR 238.103). Section 10(f) of the Home Owners' Loan Act, as amended (HOLA), 12 U.S.C. 1467a(f), provides that every subsidiary savings association of an SLHC shall give the Board at least 30 days' advance notice of the proposed declaration by its directors of any stock dividend. The obligation to respond is mandatory, as described in the previous paragraph, and the Federal Reserve is authorized to collection this information by section 10(f) of HOLA. The FR 1583 collects information concerning the amount of capital that an SLHC's subsidiary savings association intends to distribute. Specifically, the form asks for the name and address of the savings association, the date of the filing, the nature and amount of the proposed dividend declaration, and the names and signatures of the executive officer and secretary of the savings association. The information collected on the FR 1583 is generally not considered confidential. It is possible that a savings association or SHLC could seek confidential treatment under FOIA exemption 4 for the nature and amount of the proposed dividend declaration, in which case the institution would need to submit a request stating that disclosure of the specific information would likely result in substantial harm to its competitive position and demonstrating the specific nature of the harm that would result from public release of the information. FOIA exemption 4 covers commercial or financial information obtained from a person that is privileged or confidential. The determination of whether confidential treatment should be granted will have be made on a case-by-case basis.

Current Actions: On June 1, 2016, the Federal Reserve published a notice in the **Federal Register** (81 FR 35015) requesting public comment for 60 days on the extension, with revision, of the FR 1583. The comment period for this notice expired on August 1, 2016. The Federal Reserve did not receive any comments. The revisions will be implemented as proposed.

Board of Governors of the Federal Reserve System, August 11, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–19567 Filed 8–16–16; 8:45 am]

BILLING CODE 6210–01–P

FEDERAL RESERVE SYSTEM

Change in Bank Control Notices; Acquisitions of Shares of a Bank or Bank Holding Company

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire shares of a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. The notices also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than September 1, 2016.

A. Federal Reserve Bank of Chicago (Colette A. Fried, Assistant Vice President) 230 South LaSalle Street, Chicago, Illinois 60690–1414:

1. *John Ruan III, Des Moines, Iowa; Suku Radia, West Des Moines, Iowa; David J. Fisher, West Des Moines, Iowa, Thomas R. Schaefer, Stuart, Florida; and J. Landis Martin, Denver, Colorado;* together as a control group acting in concert to retain the authority to vote for all of the voting shares of BTC Financial Corporation, Des Moines, Iowa, and thereby indirectly control Bankers Trust Company, Des Moines, Iowa. Messrs. Ruan, Radia, Fisher, Schaefer and Martin constitute the Family Business Advisory Board of both The Ruan Trust and The Ruan BTC Trust, both of Des Moines, Iowa, which own all of the voting shares of BTC Financial Corporation. John Ruan III is the trustee of both Trusts.

Board of Governors of the Federal Reserve System, August 12, 2016.

Robert deV. Frierson,

Secretary of the Board.

[FR Doc. 2016–19619 Filed 8–16–16; 8:45 am]

BILLING CODE 6210–01–P

GENERAL SERVICES ADMINISTRATION

[Notice–MA–2016–06; Docket No. 2016–0002; Sequence 21]

Maximum Per Diem Reimbursement Rates for the Continental United States (CONUS)

AGENCY: Office of Government-wide Policy (OGP), General Services Administration (GSA).

ACTION: Notice of GSA Per Diem Bulletin FTR 17–01, Fiscal Year (FY) 2017 Continental United States (CONUS) per diem reimbursement rates.

SUMMARY: The General Services Administration's Fiscal Year (FY) 2017 per diem reimbursement rates review has resulted in lodging and meal allowance changes for certain locations within CONUS to provide for reimbursement of Federal employees' subsistence expenses while on official travel.

DATES:

Effective: August 17, 2016.

Applicability: This notice applies to travel performed on or after October 1, 2016, through September 30, 2017.

FOR FURTHER INFORMATION CONTACT: For clarification of content, contact Ms. Jill Denning, Program Analyst, Office of Government-wide Policy, Office of Asset and Transportation Management, at 202–208–7642, or by email at *travelpolicy@gsa.gov.* Please cite Notice of GSA Per Diem Bulletin FTR 17–01.

SUPPLEMENTARY INFORMATION:

Background: The CONUS per diem reimbursement rates prescribed in Bulletin 17–01 may be found at *www.gsa.gov/perdiem.* GSA bases the maximum lodging allowance rates on the average daily rate that the lodging industry reports to an independent organization. If a maximum lodging allowance rate, and/or a meals and incidental expenses (M&IE) per diem reimbursement rate, is insufficient to meet necessary expenses in any given location, Federal executive agencies can request that GSA review that location.

Please review numbers six and seven of GSA's per diem Frequently Asked Questions at (*www.gsa.gov/perdiemfaqs*) for more information on the special review process. In addition, the Federal Travel Regulation (FTR) allows for actual expense reimbursement as provided in §§ 301–11.300 through 301–11.306. For FY2017, no new non-standard area locations were added. The standard CONUS lodging allowance rate will increase from $89 to $91. The M&IE reimbursement rate tiers were not revised for FY2017. GSA issues and publishes the CONUS per diem rates, formerly published in Appendix A to 41 CFR Chapter 301, solely on the Internet at *www.gsa.gov/perdiem.*

GSA also now solely publishes the M&IE meal breakdown table, which is used when employees are required to deduct meals from their M&IE reimbursement pursuant to FTR § 301–11.18, at *www.gsa.gov/mie.* This process, implemented in 2003 for per diem reimbursement rates, and in 2015 for the M&IE breakdown table, ensures more timely changes in per diem reimbursement rates established by GSA for Federal employees on official travel within CONUS. Notices published periodically in the **Federal Register**, such as this one, now constitute the only notification of revisions in CONUS per diem reimbursement rates to agencies, other than the changes posted on the GSA Web site.

Dated: August 11, 2016.

Troy Cribb,

Associate Administrator, Office of Government-wide Policy.

[FR Doc. 2016–19563 Filed 8–16–16; 8:45 am]

BILLING CODE 6820–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30 Day–16–0199]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) has submitted the following information collection request to the Office of Management and Budget (OMB) for review and approval in accordance with the Paperwork Reduction Act of 1995. The notice for the proposed information collection is published to obtain comments from the public and affected agencies.

Written comments and suggestions from the public and affected agencies concerning the proposed collection of information are encouraged. Your comments should address any of the following: (a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility; (b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) Enhance the quality, utility, and clarity of the information to be collected; (d) Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses; and (e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570 or send an email to *omb@cdc.gov.* Written comments and/or suggestions regarding the items contained in this notice should be directed to the Attention: CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Importation of Etiologic Agents (42 CFR 71.54) (OMB Control No. 0920–0199, exp. 1/31/2017)—Extension—Office of Public Health Preparedness and Response (OPHPR), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

Section 361 of the Public Health Service Act (42 U.S.C. 264), as amended, authorizes the Secretary of Health and Human Services to make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F—Importations—contains provisions for the importation of infectious biological agents, infectious substances, and vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC.

CDC requests Office of Management and Budget approval to collect information for three years using the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States and Application for a Permit to Import or Transport Live Bats. We are also requesting a title change to read—*Application for Permit to Import Infectious Biological Agents into the United States.*

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States form is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to make no changes to this application.

The Application for Permit to Import or Transport Live Bats form is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC plans to make no changes to this application.

Estimates of burden for the survey are based on information obtained from the CDC import permit database on the number of permits issued on annual basis since 2010. The total estimated burden for the one-time data collection is 545 hours. There are no costs to respondents except their time.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hrs.)
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors.	Application for Permit to Import Infectious Biological Agents into the United States.	1625	1	20/60
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats ..	10	1	20/60

Jeffrey M. Zirger,

Health Scientist, Acting Chief, Information Collection Review Office, Office of Scientific Integrity, Office of the Associate Director for Science, Office of the Director, Centers for Disease Control and Prevention.

[FR Doc. 2016–19598 Filed 8–16–16; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Title: Migrant and Seasonal Head Start Study.

OMB No.: New Collection.

Description: The Office of Planning, Research and Evaluation (OPRE), Administration for Children and Families (ACF), U.S. Department of Health and Human Services, is proposing an information collection activity for the Migrant and Seasonal Head Start (MSHS) Study.

The MSHS Study is a nationally representative study that will describe the characteristics and experiences of the children and families who enroll in MSHS and the practices and services of the MSHS programs that serve them. The findings will provide essential up-to-date information to the Office of Head Start, other federal government agencies, local MSHS programs, and the public. The study will be the first national MSHS study to include direct child assessments, which will provide valuable information about MSHS children that programs can use to inform program, center and classroom practices.

Data collection will involve mail surveys to selected MSHS center directors and all MSHS program directors nationwide about operational characteristics, program- and center-level policies and practices, and services and resources offered to MSHS families. The study will also conduct on-site data collection with children, parents, teachers, and classrooms in a nationally-representative sample of MSHS centers. The on-site data collection will include classroom observations, teacher surveys, child reports and child assessments to obtain information on classroom instruction and practices, children's abilities and families' well-being.

Respondents: MSHS program directors, center directors, teachers, assistant teachers, parents, and children.

ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Number of responses per respondent	Average burden hours per response	Estimated annual burden hours
Program Director survey	53	1	0.67	36
Center Director survey	253	1	0.67	170
Call script for Program Directors	24	1	1	24
Form for Program Directors to verify key information for selected centers ..	24	1	0.5	12
Call script for Center Directors	53	1	1	53
Call script for On Site Coordinators	53	1	1	53
Classroom sampling form	53	1	0.5	27
Data collection coordination efforts	53	1	20	1,060
Child roster form	53	3	0.25	40
Teacher survey	159	1	0.67	107
Teacher child report	159	8	0.17	216
Assistant Teacher survey	159	1	0.33	52
Parent consent form	1,018	1	0.25	255
Child assessments (preschoolers and older toddlers only)	848	1	0.67	568
Parent interview (including Parent child report)	1,018	1	1	1,018
Estimated Total Annual Burden Hours:	....	....	....	3,689

In compliance with the requirements of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 330 C Street SW., Washington, DC 20201, Attn: OPRE Reports Clearance Officer. Email address: *OPREinfocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

ACF Certifying Officer.

[FR Doc. 2016–19611 Filed 8–16–16; 8:45 am]

BILLING CODE 4184–22–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–D–0800]

Regulatory Classification of Pharmaceutical Co-Crystals; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a draft guidance for industry entitled "Regulatory Classification of Pharmaceutical Co-Crystals." This guidance provides applicants planning to submit new drug applications (NDAs) and abbreviated new drug applications (ANDAs) with information on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms. This guidance also provides information about the data that applicants should submit to support the appropriate classification of a co-crystal as well as the regulatory implications of the classification. This draft guidance revises the guidance for industry entitled "Regulatory Classification of Pharmaceutical Co-Crystals" issued in April 2013.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 17, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2011–D–0800 for "Regulatory Classification of Pharmaceutical Co-Crystals." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the draft guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New

Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Richard (Rik) Lostritto, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 4148, Silver Spring, MD 20993–0002, 301–796–1697.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Regulatory Classification of Pharmaceutical Co-Crystals." This guidance provides NDA and ANDA applicants with information on the appropriate regulatory classification of pharmaceutical co-crystal solid-state forms.

Co-crystals are crystalline materials composed of two or more different molecules, typically drug and co-crystal formers ("coformers"), in the same crystal lattice. Pharmaceutical co-crystals have opened up opportunities for engineering solid-state forms beyond conventional solid-state forms of an active pharmaceutical ingredient (API), such as salts and polymorphs. Co-crystals can be tailored to enhance drug product bioavailability and stability and to enhance the processability of APIs during drug product manufacture. Another advantage of co-crystals is that they generate a diverse array of solid-state forms for APIs that lack ionizable functional groups, which is a prerequisite for salt formation.

This guidance revises the guidance for industry "Regulatory Classification of Pharmaceutical Co-Crystals" issued in April 2013, which classifies co-crystals as a drug product intermediate (or as an in-process material). This classification has contributed to uncertainty regarding the interpretation of the guidance because in a commercial setting, co-crystals are typically manufactured in drug substance facilities, yet when classified as a drug product intermediate, additional current good manufacturing practice requirements apply. Therefore, the guidance has not been conducive to the development of co-crystals. In response to this and other feedback from stakeholders, FDA has reconsidered the appropriate classification of co-crystals. This revision addresses the concern by providing information on the appropriate classification of co-crystal solid-state forms, the data that should be submitted to support the classification, and the regulatory implications of such a classification.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on regulatory classification of pharmaceutical co-crystals. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. The Paperwork Reduction Act of 1995

This guidance refers to previously approved collections of information found in FDA regulations. This guidance refers to information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR 314.50(d)(1) and 314.94(a)(5) and (a)(9) have been approved under OMB control number 0910–0001.

III. Electronic Access

Persons with access to the Internet may obtain the draft guidance at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 11, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19596 Filed 8–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2011–N–0144]

Agency Information Collection Activities; Submission for Office of Management and Budget Review Comment Request; Voluntary Qualified Importer Program Guidance for Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by September 16, 2016.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–NEW and title, "Voluntary Qualified Importer Program Guidance for Industry." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: FDA PRA Staff, Office of Operations, Food and Drug Administration, Three White Flint North, 11601 Landsdown St., 10A63, North Bethesda, MD 20852, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

FDA's Voluntary Qualified Importer Program (VQIP); Guidance for Industry OMB Control Number 0910—NEW

The FDA Food Safety Modernization Act (FSMA) (Pub. L. 111–353) enables FDA to better protect public health by helping to ensure the safety and security of the food supply. It enables FDA to focus more on preventing food safety problems rather than relying primarily on reacting to problems after they occur. FSMA recognizes the important role industry plays in ensuring the safety of the food supply, including the adoption of modern systems of preventive controls in food production. Under FSMA, those that import food have a responsibility to ensure that their suppliers produce food that meets U.S. safety standards.

FSMA also requires FDA to establish a voluntary, fee-based program for the expedited review and importation of foods by importers who achieve and maintain a high level of control over the safety and security of their supply chains. This control includes importation of food from facilities that have been certified under FDA's accredited third-party audit program, as well as other measures that support a high level of confidence in the safety and security of the food they import. Expedited entry incentivizes importers to adopt a robust system of supply chain management and further benefits public health by allowing FDA to focus its resources on food entries that pose a higher risk to public health.

Section 302 of FSMA amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act) by adding new section 806, Voluntary Qualified Importer Program (21 U.S.C. 384b). Section 806(a)(1) of the FD&C Act directs FDA to establish this voluntary program for the expedited review and importation of food, and to establish a process for the issuance of a facility certification to accompany food offered for importation by importers participating in VQIP. Section 806(a)(2) directs FDA to issue a guidance document related to participation in, revocation of such participation in, reinstatement in, and compliance with VQIP.

Accordingly, in the **Federal Register** of June 5, 2015 (80 FR 32136), FDA published a notice announcing the availability of a draft guidance entitled "FDA's Voluntary Qualified Importer Program," and invited public comment regarding the guidance as well as the information collection provisions associated with the guidance (80 FR 32136 at 32138). In response to the solicitation of comments regarding the information collection provisions, the Agency received multiple comments. Two comments suggested that FDA's recordkeeping and reporting estimates were too low. Because neither comment provided justification for why the burden calculation might be too low or offered alternative calculations, we have retained our original estimates noting that, upon implementation of the program, we will again invite public comment on the information collection burden and make adjustments to our estimates accordingly. One comment attributed costs to the information collection but did not provide a basis for the calculations provided. We therefore have not adopted the comment, but again note that public input will be solicited on the information collection upon implementation of the program.

Finally, one comment objected to the provision regarding respondents obtaining a Dun & Bradstreet (D&B) Data Universal Numbering System (DUNS) number and providing it to the Agency. We have determined that the DUNS number is an appropriate unique facility identifier during Foreign Supplier Verification Program (FSVP) rulemaking. We expect that most VQIP importers will also be FSVP importers and will have obtained a DUNS number.

Description of Respondents: Respondents to the collection are importers of human or animal food.

We estimate the burden for the collection of information as follows:

TABLE 1—ESTIMATED ONE-TIME RECORDKEEPING BURDEN [1]

Information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total one-time records	Average burden per recordkeeping	Total hours
Quality Assurance Program (QAP) preparation	200	1	200	160	32,000

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

We estimate it will take a VQIP applicant no longer than 10 hours to develop its QAP, including compiling its company profile, organizational structure, corporate quality policy statement, procedures for QAP implementation, food safety and food defense policies and procedures, and procedures for record retention. On average, the preparation of a QAP by a VQIP applicant is estimated at approximately 160 hours (110 + 40 + 10). In estimation of the one-time recordkeeping burden to prepare a QAP manual, we assume that VQIP importers do not already have a similar manual in place (*e.g.*, food safety plan under the Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food regulation (21 CFR part 117); food defense plan under the Focused Mitigation Strategies to Protect Food Against Intentional Adulteration regulation (IA regulation) (21 CFR part 121)). The one-time recordkeeping burden for 200 VQIP applicants to prepare QAPs is estimated at 32,000 hours (200 applicants × 160 hours/applicant) (see table 1). To the extent that some importers do have QAP manuals in place, the burden would be overestimated.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

Information collection activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
QAP modification	200	1	200	16	3,200

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

A VQIP importer is expected to update its QAP on an ongoing basis. We estimate it would take 10 percent of the effort to prepare the QAP, or 16 hours, to update the QAP each year. Therefore, we estimate the annual recordkeeping burden of modification of the QAP for 200 VQIP importers at 3,200 hours (200 importers × 16 hours/importer). The VQIP food defense security criterion is similar to the Food Defense Plan requirement under § 121.126 (21 CFR 121.126) in the IA regulation. Under the IA regulation, the food defense plan must include the written identification of actionable process steps, focused mitigation strategies, procedures for monitoring, corrective action procedures, and verification procedures. Therefore, we estimate that, on average, it would take 40 hours for an applicant to prepare the food defense portion of the VQIP QAP.

TABLE 3—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Information collection activity	Number of respondents	Number of responses per respondent	Total one-time responses	Average burden per response	Total hours
Initial VQIP application	100	1	100	80	8,000
Initial VQIP application w/additional information	100	1	100	100	10,000
Total					18,000

[1] There are no capital or operating and maintenance costs associated with the collection of information.

The guidance will inform food importers of application procedures for VQIP. We estimate that up to 200 qualified importers will be accepted in the first year of VQIP. We estimate that it will take 80 person-hours to compile all the relevant information and complete the application for the VQIP program. For the purpose of this analysis, we assume that 50 percent of all applications received will require additional information and it would take an additional 20 person-hours by the importer to provide that information. Therefore, we estimate that 100 importers will spend 8,000 hours (80 hours/importer × 100 importers) and 100 importers will spend 10,000 hours (100 hours/importer × 100 importers) to submit their initial VQIP applications for a total one-time reporting burden of 18,000 hours (see table 3).

TABLE 4—ESTIMATED ANNUAL REPORTING BURDEN [1]

Information collection activity	Number of responses	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subsequent year VQIP application	200	1	200	20	4,000
Request to reinstate participation	2	1	2	10	20
Total					4,020

[1] There are no capital or operating and maintenance costs associated with the collection of information.

The guidance states that each VQIP participant will submit to FDA a notice of intent to participate in VQIP on an annual basis. We expect that each of the expected 200 importers in VQIP would apply in the subsequent year to participate in VQIP. We expect that an application to participate in VQIP in a subsequent year will take significantly less time to prepare than the initial application. We use 25 percent of the amount of effort to prepare and submit the initial application for acceptance in VQIP. Therefore, it is expected that, on average, each VQIP importer will spend 20 hours to complete and submit a VQIP application for each subsequent year. The annual burden of completing a subsequent year application to participate in VQIP status by 200 importers is estimated at 4,000 hours (200 applications × 20 hours/application) (see table 4).

Finally, we have added to the VQIP estimated annual reporting burden an estimate of the burden associated with importers' requests to reinstate participation in VQIP after their participation is revoked. We believe most participants will not need to use this provision, and we have included an estimate that reflects this. Upon implementation of the VQIP, we will reevaluate our estimate for future OMB submission and revise it accordingly.

Dated: August 12, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19643 Filed 8–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–5073]

Use of Nucleic Acid Tests To Reduce the Risk of Transmission of Hepatitis B Virus From Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a document entitled "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry." The guidance document provides establishments that make donor eligibility determinations for donors of human cells, tissues, and cellular and tissue-based products (HCT/Ps), with recommendations concerning the use of FDA-licensed nucleic acid tests (NAT) in donor testing for hepatitis B virus (HBV) deoxyribonucleic acid (DNA). The guidance finalizes the draft guidance of the same title dated January 2016 and supplements previous FDA recommendations to HCT/P establishments concerning donor testing for hepatitis B surface antigen (HBsAg) and total antibody to hepatitis B core antigen (anti-HBc), in the document entitled "Guidance for Industry: Eligibility Determination for Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products (HCT/Ps)" dated August 2007 (2007 Donor Eligibility Guidance).

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA–2015–D–5073 for "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Submit written requests for single copies of the guidance to the Office of Communication, Outreach, and Development, Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 3128, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling CBER at 1–800–835–4709 or 240–402–8010. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Angela Moy, Center for Biologics Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 71, Rm. 7301, Silver Spring, MD 20993–0002, 240–402–7911.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a document entitled "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products; Guidance for Industry." The guidance provides establishments that make donor eligibility determinations for donors of HCT/Ps, with recommendations concerning the use of FDA-licensed NAT in donor testing for HBV DNA. FDA considers the use of FDA-licensed HBV NAT in testing HCT/P donors to be necessary to adequately and appropriately reduce the risk of transmission of HBV. The FDA-licensed HBV NAT can detect evidence of the viral infection at an earlier stage than the HBsAg and total anti-HBc tests. Therefore, FDA recommends the use of FDA-licensed HBV NAT for testing donors of HCT/Ps for evidence of infection with HBV.

HBV is a major global public health concern and has been transmitted by blood transfusions and tissue transplantation. Available literature has indicated possible transmissions of HBV by hematopoietic stem cells and blood with HBV NAT positive/hepatitis B surface antibody (anti-HBs) positive/HBsAg negative blood, irrespective of anti-HBc test results. In blood donors, adding the HBV NAT testing for HBV reduces the residual risk of transmission of HBV infection beyond that which can be achieved by screening donors using only HBsAg and total anti-HBc tests. In addition, it can detect breakthrough infections in previously vaccinated individuals who are exposed to the virus, and HBV mutants appear to be more likely detected by HBV NAT than by HBsAg assays.

In the United States, there are currently FDA-licensed HBV NAT assays intended to screen blood samples from donors of whole blood and blood components, other living donors (individual organ donors when specimens are obtained while the donor's heart is still beating), and blood specimens from cadaveric (non-heart-beating) donors. Some of these are multiplex assays that can simultaneously detect HIV, HCV, and HBV in a single blood specimen, thus improving the feasibility of routine NAT testing for HBV. By analogy to the experience in the blood donor setting, it is reasonable to expect that the residual risk of transmission of HBV infection would be reduced by adding HBV NAT to the testing strategy for HCT/P donors. HBV NAT's potential utility in further reducing risk of HBV transmission by transplantation is mainly restricted to the early HBsAg-negative phase of infection. In summary, the available scientific data and the availability of FDA-licensed assays support a recommendation that all HCT/P donors should be tested using an FDA-licensed HBV NAT.

In the **Federal Register** of January 8, 2016 (81 FR 937), FDA announced the availability of the draft guidance of the same title dated January 2016. FDA received a few comments on the draft guidance and those comments were considered as the guidance was finalized. The guidance announced in this notice finalizes the draft guidance of the same title dated January 2016 and supplements previous FDA recommendations to HCT/P establishments concerning donor testing for HBsAg and total antibody to anti-HBc, in the 2007 Donor Eligibility Guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the "Use of Nucleic Acid Tests to Reduce the Risk of Transmission of Hepatitis B Virus from Donors of Human Cells, Tissues, and Cellular and Tissue-Based Products." It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: August 11, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2016–19588 Filed 8–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0567]

Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice, establishment of a public docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee of the Pediatric Advisory Committee. The general function of the committee is to provide advice and recommendations to the Agency on FDA's regulatory issues. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held on September 14, 2016, from 8 a.m. to 5:30 p.m.

ADDRESSES: DoubleTree by Hilton Hotel Bethesda-Washington DC, 8120 Wisconsin Ave., Bethesda, MD 20814, 301–652–2000. Answers to commonly asked questions including information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at *www.doubletreebethesda.com/.* You may submit your comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party many not wish to be posted, such as medical information, you or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions".

Instructions: All submissions received must include either the Docket No. FDA–2016–N–0567 for the "Pediatric Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments"; or the Docket No. FDA–2016–N–2470 for the "Pediatric-focused Safety Reviews", which will be posted on the Internet, but not presented at the Pediatric Advisory Committee meeting. Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information thatyou do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION". The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential". Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Marieann Brill, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993, 240–402–3838, *marieann.brill@fda.hhs.gov* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting. For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

SUPPLEMENTARY INFORMATION: *Agenda:* On September 14, 2016, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric-focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). Comments about the up-coming September advisory committee meeting should be submitted to Docket No. FDA–2016–N–0567.

The PAC will meet to discuss the following products (listed by FDA Center):

1. Center for Biologics Evaluation and Research
    a. MENVEO (Meningococcal (groups A, C, Y and W–135) Oligosaccharide Diphtheria CRM197 Conjugate Vaccine)
    b. IXIARO (Japanese encephalitis vaccine)
2. Center for Drug Evaluation and Research
    a. ASACOL & ASACOL HD (mesalamine)
    b. BLOXIVERZ (neostigmine methylsulfate)
    c. DELZICOL (mesalamine)
    d. DORYX (doxycycline hyclate)
    e. KARBINAL ER (carbinoxamine maleate)
    f. KEPIVANCE (palifermin)
    g. SUSTIVA (efavirenz)
    h. TOPAMAX (topiramate)
    i. XOLAIR (omalizumab)
3. Center for Devices and Radiological Health
    a. ELANA SURGICAL KIT (HUD)
    b. BERLIN HEART EXCOR® Pediatric Ventricular Assist Device (VAD)
    c. ENTERRA™ THERAPY SYSTEM
    d. CONTEGRA PULMONARY VALVED CONDUIT
    e. PLEXIMMUNE

FDA will also provide an update of their additional ongoing analysis of a possible safety signal regarding the use of the drug product Exjade (deferasirox) in children with fever and dehydration that was discussed at the September 2015 PAC meeting.

For the products to be discussed at the PAC meeting, FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material will be available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before September 7, 2016. Oral presentations from the public will be scheduled between approximately 8:30 a.m. to 9:30 a.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before August 30, 2016. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by August 31, 2016.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA is establishing a docket for public comment for the PAC meeting. The docket number is FDA–2016–N–0567. The docket will close on August 31, 2016. Comments received on or before August 31, 2016, will be provided to the committee. Comments received after the date will be taken into consideration by the Agency.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marieann Brill at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Additional Pediatric-focused Safety Reviews: FDA will make available additional pediatric safety review reports for selected products at *http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/ucm510701.htm*. FDA is establishing a second public docket to receive input on additional pediatric-focused safety reviews that will be posted on the Internet. The docket number is FDA–2016–N–2470; the docket will open on September 12, 2016, and remain open until September 23, 2016. These safety review reports are for the following products:

1. BARACLUDE (entecavir)
2. ISENTRESS (raltegravir potassium)
3. LYSTEDA (tranexamic acid)
4. SALONPAS Pain Relief Patch (methyl salicylate 10% and l-menthol 3%).

Dated: August 11, 2016.

Janice M. Soreth,

Acting Associate Commissioner, Special Medical Programs.

[FR Doc. 2016–19589 Filed 8–16–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Indian Health Outreach and Education II Program; Correction

AGENCY: Indian Health Service, HHS.

ACTION: Notice; correction.

SUMMARY: The Indian Health Service published a document in the **Federal Register** on July 15, 2016, for the Fiscal Year 2016 National Indian Health Outreach and Education II Program. The notice contained an incorrect Announcement Number.

FOR FURTHER INFORMATION CONTACT: Ms. Michelle EagleHawk, Deputy Director, Office of Direct Service and Contracting Tribes, 5600 Fishers Lane, Mail Stop: 8E17, Rockville, Maryland 20857, Telephone: (301) 443–1104, email:

Michelle.EagleHawk@ihs.gov. (This is not a toll-free number.)

Correction

In the **Federal Register** of July 15, 2016, FR Doc. 2016–16819, on page 46100, in the second column at the top of the page, the correct Announcement Number should read as follows:

Announcement Number: HHS–2016–IHS–NIHOE–2–BH–HIV–AIDS–0001.

Dated: August 4, 2016.

Elizabeth A. Fowler,

Deputy Director for Management Operations, Indian Health Service.

[FR Doc. 2016–19597 Filed 8–16–16; 8:45 am]

BILLING CODE 4165–16–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Special Emphasis Panel; Worm Intervention Test Data Sharing.

Date: September 19, 2016.

Time: 3:00 p.m. to 3:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Worm Intervention Test One.

Date: September 19, 2016.

Time: 12:00 p.m. to 3:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Bita Nakhai, Ph.D., Scientific Review Branch, National Institute on Aging, Gateway Bldg., 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20814, 301–402–7701, *nakhaib@nia.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; NIH Phase III Clinical Trials for Alzheimer's Disease and Other Age-Related Cognitive Declines.

Date: October 13, 2016.

Time: 12:01 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Maurizio Grimaldi, MD, Ph.D., Scientific Review Officer, National Institute on Aging, National Institutes of Health, 7201 Wisconsin Avenue, Room 2C218, Bethesda, MD 20892, 301–496–9374, *grimaldim2@mail.nih.gov.*

Name of Committee: National Institute on Aging Special Emphasis Panel; Alzheimer's Disease Drug Development.

Date: October 14, 2016.

Time: 12:00 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute on Aging, Gateway Building, Suite 2W200, 7201 Wisconsin Avenue, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Alexander Parsadanian, Ph.D., Scientific Review Officer, National Institute on Aging, Gateway Building 2C/212, 7201 Wisconsin Avenue, Bethesda, MD 20892, 301–496–9666, *parsadaniana@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS).

Dated: August 11, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19547 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Center for Advancing Translational Sciences Special Emphasis Panel; CTSA Review.

Date: September 22–23, 2016.

Time: 8:00 a.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Hilton Washington DC/Rockville Hotel, Plaza 2 and 3, 1750 Rockville Pike, Rockville, MD 20852.

Contact Person: Carol Lambert, Ph.D., Acting Deputy Director, Office of Scientific Review, National Center for Advancing Translational Sciences (NCATS), National Institutes of Health, 6701 Democracy Blvd., Democracy 1, Room 1076, Bethesda, MD 20892, 301–435–0814, *lambert@mail.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.859, Pharmacology, Physiology, and Biological Chemistry Research; 93.350, B—Cooperative Agreements; 93.859, Biomedical Research and Research Training, National Institutes of Health, HHS)

Dated: August 11, 2016.

David Clary,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19542 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. The meeting will also be videocast and can be accessed from the NIH Videocasting and Podcasting Web site (*http://videocast.nih.gov/*).

Name of Committee: National Cancer Institute Clinical Trials and Translational Research Advisory Committee.

Date: November 2, 2016.

Time: 8:00 a.m. to 4:00 p.m.

Agenda: Strategic Discussion of NCI's Clinical and Translational Research Programs.

Place: National Institutes of Health, Building 31, C-Wing, 6th Floor, Room 9 and 10, 31 Center Drive, Bethesda, MD 20892.

Contact Person: Sheila A. Prindiville, MD, MPH, Director, Coordinating Center for Clinical Trials, National Institutes of Health, National Cancer Institute, 9609 Medical Center Drive, Room 6W136, Rockville, MD 20850, 240–276–6173, *prindivs@mail.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *http://deainfo.nci.nih.gov/advisory/ctac/ctac.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: August 11, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19543 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Advisory Environmental Health Sciences Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Advisory Environmental Health Sciences Council.

Date: September 13, 2016.

Closed: September 13, 2016, 8:30 a.m. to 9:30 a.m.

Agenda: To review and evaluate grant applications.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Open: September 13, 2016, 9:30 a.m. to 4:15 p.m.

Agenda: Discussion of program policies and issues.

Place: Nat. Inst. of Environmental Health Sciences, Building 101, Rodbell Auditorium, 111 T. W. Alexander Drive, Research Triangle Park, NC 27709.

Contact Person: Gwen W. Collman, Ph.D., Director, Division of Extramural Research & Training, National Institutes of Health, Nat. Inst. of Environmental Health Sciences, 615 Davis Dr., KEY615/3112, Research Triangle Park, NC 27709, (919) 541–4980, *collman@niehs.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

Information is also available on the Institute's/Center's home page: *http://www.niehs.nih.gov/about/boards/naehsc/,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: August 10, 2016.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19548 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the National Heart, Lung, and Blood Advisory Council.

The meeting will be open to the public as indicated below, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting.

Name of Committee: National Heart, Lung, and Blood Advisory Council.

Date: September 20, 2016.

Open: 1:00 p.m. to 5:00 p.m.

Agenda: To discuss program policies and issues.

Place: National Institutes of Health, Building 35A, Porter Building, Room 640, 35A Convent Drive, Bethesda, MD 20892.

Contact Person: Valerie L. Prenger, Ph.D., MPH, Acting Division Director, Division of Extramural Research Activities, National Heart, Lung, and Blood Institute, 6701 Rockledge Drive, Room 7214, Bethesda, MD 20892–7924, 301–435–0270, *prengerv@nhlbi.nih.gov.*

Any interested person may file written comments with the committee by forwarding the statement to the Contact Person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person.

In the interest of security, NIH has instituted stringent procedures for entrance onto the NIH campus. All visitor vehicles, including taxicabs, hotel, and airport shuttles will be inspected before being allowed on campus. Visitors will be asked to show one form of identification (for example, a government-issued photo ID, driver's license, or passport) and to state the purpose of their visit.

Information is also available on the Institute's/Center's home page: *www.nhlbi.nih.gov/meetings/nhlbac/index.htm,* where an agenda and any additional information for the meeting will be posted when available.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: August 11, 2016.

Michelle Trout,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19545 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Advisory Board, September 07, 2016, 09:00 a.m. to September 07, 2016, 5:00 p.m., National Institutes of Health, Building 31, 31 Center Drive, Conference Room 10, Bethesda, MD 20892 which was published in the **Federal Register** on August 08, 2016, 81 FR 52452.

This meeting notice has been amended to change the end time of the open session to 2:45 p.m. The closed session has also been amended to begin at 3:00 p.m. and end at 4:15 p.m. The meeting is partially closed to the public.

Dated: August 11, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19544 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of Exclusive Patent License: Development of T Cell Receptors (TCRs) Targeting the KRAS G12D Mutation for the Treatment of Cancer

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: This is notice, in accordance with 35 U.S.C. 209 and 37 CFR part 404, that the National Cancer Institute, National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an exclusive patent license to Kite Pharma, Inc. (''Kite'') located in Santa Monica, CA to practice the inventions embodied in the following patent applications:

Intellectual Property

United States Provisional Patent Application No. 62/084,654, filed November 26, 2014, entitled ''Anti-mutated KRAS T Cell Receptors'' [HHS Reference No. E–028–2015/0–US–01]; and

PCT Application No. PCT/US2015/062269 filed November 24, 2015 entitled ''Anti-mutated KRAS T Cell Receptors'' [HHS Reference No. E–028–2015/1–PCT–01].

The patent rights in these inventions have been assigned to the government of the United States of America. The prospective exclusive license territory may be worldwide and the field of use may be limited to the development, manufacture and commercialization of retrovirally-engineered mutated KRAS TCR-based autologous peripheral blood T cell therapy products as set forth in the Licensed Patent Rights for the treatment of human cancers.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute on or before September 1, 2016 will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated exclusive license should be directed to: Andrew Burke, Ph.D., Licensing and Patenting Manager, Technology Transfer Center, National Cancer Institute, 9609 Medical Center Drive, MSC 9702, Rockville, MD 20852; Telephone: (240) 276–5484; Email *andy.burke@nih.gov.*

SUPPLEMENTARY INFORMATION: The present invention describes an isolated T cell receptor (TCR) which recognizes the G12D mutation of the Kristen rat sarcoma viral oncogene homolog (KRAS) protein within the context of major histocompatibility complex HLA–A11 presentation.

KRAS is an oncogene with a well-characterized role in the formation of several human cancers, including: Pancreatic, colorectal and lung. Certain mutations, such as the substitution of aspartic acid or valine for glycine at codon 12 (termed G12D and G12V, respectively), occur at relatively high frequency and may represent amenable targets for immunotherapies. Due to the restricted expression of KRAS G12D in pre-cancerous and malignant cells, engineered T cell therapies based on the present invention may be useful for the treatment of select cancers.

The prospective exclusive license will be royalty bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the NCI receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

Complete applications for a license in an appropriate field of use that are timely filed in response to this notice will be treated as objections to the grant of the contemplated exclusive license. Comments and objections submitted to this notice will not be made available for public inspection and, to the extent permitted by law, will not be released under the Freedom of Information Act, 5 U.S.C. 552.

Dated: August 8, 2016.

Richard U. Rodriguez,

Associate Director, Technology Transfer Center, National Cancer Institute.

[FR Doc. 2016–19549 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute on Aging Initial Review Group; Neuroscience of Aging Review Committee.

Date: September 29–30, 2016.

Time: 4:00 p.m. to 12:00 p.m.

Agenda: To review and evaluate grant applications.

Place: DoubleTree by Hilton Bethesda, 8120 Wisconsin Ave., Bethesda, MD 20814.

Contact Person: Jeannette L. Johnson, Ph.D., Deputy Review Branch Chief, National Institutes of Health, National Institute on Aging, Gateway Building, Bethesda, MD

20892, 301–402–7705, *johnsonj9@nia.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: August 11, 2016.

Melanie J. Gray,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2016–19546 Filed 8–16–16; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5909–N–60]

30-Day Notice of Proposed Information Collection: Public Housing Agency (PHA) Lease and Grievance Requirements

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* September 16, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on March 4, 2016 at 81 FR 11584.

A. Overview of Information Collection

Title of Information Collection: Public Housing Agency (PHA) Lease and Grievance Requirements.

OMB Approval Number: 2577–0006.

Type of Request: Reinstatement of currently approved collection.

Form Number: None.

Description of the need for the information and proposed use: The Public Housing lease and grievance procedures are a recordkeeping requirement on the part of Public Housing agencies (PHAs) as they are required to enter into and maintain lease agreements for each individual or family that occupies a Public Housing unit. Also, both PHAs and tenants are required to follow the protocols set forth in the grievance procedures for both an informal and formal grievance hearing. This information collection is a revision of the previous submission. The reduction in burden hours is attributable to a fewer number of tenants in public housing covered by these lease and grievance procedures.

Respondents (*i.e.*, affected public): Public Housing Authorities (PHAs).

Estimated Number of Respondents: 945,539.

Estimated Number of Responses: 1,359,284.

Frequency of Response: 1.

Average Hours per Response: .25.

Total Estimated Burden: 330,939 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 9, 2016.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2016–19640 Filed 8–16–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5909–N–59]

30-Day Notice of Proposed Information Collection: Energy and Performance Information Center (EPIC)

AGENCY: Office of the Chief Information Officer, HUD.

ACTION: Notice.

SUMMARY: HUD has submitted the proposed information collection requirement described below to the Office of Management and Budget (OMB) for review, in accordance with the Paperwork Reduction Act. The purpose of this notice is to allow for an additional 30 days of public comment.

DATES: *Comments Due Date:* September 16, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: HUD Desk Officer, Office of Management and Budget, New Executive Office Building, Washington, DC 20503; fax: 202–395–5806. Email: *OIRA_Submission@omb.eop.gov.*

FOR FURTHER INFORMATION CONTACT: Colette Pollard, Reports Management Officer, QMAC, Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email Colette Pollard at *Colette.Pollard@hud.gov* or telephone 202–402–3400. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

The **Federal Register** notice that solicited public comment on the information collection for a period of 60 days was published on April 4, 2016 at 81 FR 19234.

A. Overview of Information Collection

Title of Information Collection: Energy and Performance Information Center (EPIC).

OMB Approval Number: 2577–0274.

Type of Request: Revision of currently approved collection.

Form Number: None—all information collected electronically.

Description of the need for the information and proposed use: The Department has recognized the need for improving energy efficiency in affordable housing and has prioritized this in Agency Priority Goal #4, Measure #13. The energy efficiency data collected through EPIC gives the Department a more comprehensive dataset regarding energy efficiency. The EPIC data system will gradually automate the collection of the five year plan and annual statement forms from grantees. These are required forms presently collected in hard copy on Forms HUD 50075.1 and HUD 50075.2 under collection OMB control number 2577–0226. These forms also collect data on the eventual, actual use of funds; this data will be gradually collected electronically through the EPIC data system as well. Electronic collection will enable the Department to aggregate information about the way grantees are using Federal funding. Additionally, PHA grantees will be able to submit Replacement Housing Factor fund plans, the mechanism by which PHAs are allowed to accumulate special funds received based on units removed from the inventory from year to year. This information is presently collected in hard copy at the field office level; the EPIC data system will automate and centralize this collection in order to streamline the process and improve transparency. Furthermore, the EPIC data system will be loaded with Physical Needs Assessment ("PNA") data. This data being in the system coupled with the electronic planning process will streamline grantee planning. The EPIC data system will collect information about the Energy Performance Contract ("EPC") process, including the energy efficiency improvements. As the Department moves to shrink its energy footprint in spite of rising energy costs, clear and comprehensive data on this process will be crucial to its success. Finally, the Department has prioritized in Agency Performance Goal #2, Measure #5 making housing more available for more families. In the light of the recent housing crisis, this goal has become simultaneously more challenging and more important. Tracking of the use of Federal funds paid through the Public Housing Capital Fund, the only Federal funding stream dedicated to the capital needs of the nation's last resort housing option, is crucial to understanding how the Department can properly and efficiently assist grantees in meeting this goal as well as assessing the Department's own progress. The EPIC data system will track development of Public Housing with Federal funds and through other means, including mixed-finance development.

Respondents (*i.e. affected public*): Members of Affected Public: State, Local or Local Governments and Non-profit organizations.

Estimated Number of Respondents: 3,150.

Estimated Number of Responses: 31,800 annual responses.

Frequency of Response: 1.

Average Hours per Response: 2.19.

Total Estimated Burdens: 69,645 hours.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 9, 2016.

Colette Pollard,

Department Reports Management Officer, Office of the Chief Information Officer.

[FR Doc. 2016–19641 Filed 8–16–16; 8:45 am]

BILLING CODE 4210–67–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–5913–N–19]

60-Day Notice of Proposed Information Collection: Uniform Physical Standards & Physical Inspection Requirements

AGENCY: Office of the Assistant Secretary for Housing—Federal Housing Commissioner, HUD.

ACTION: Notice.

SUMMARY: HUD is seeking approval from the Office of Management and Budget (OMB) for the information collection described below. In accordance with the Paperwork Reduction Act, HUD is requesting comment from all interested parties on the proposed collection of information. The purpose of this notice is to allow for 60 days of public comment.

DATES: *Comments Due Date:* October 17, 2016.

ADDRESSES: Interested persons are invited to submit comments regarding this proposal. Comments should refer to the proposal by name and/or OMB Control Number and should be sent to: Colette Pollard, Reports Management Officer, QDAM, Department of Housing and Urban Development, 451 7th Street SW., Room 4176, Washington, DC 20410–5000; telephone 202–402–3400 (this is not a toll-free number) or email at *Colette.Pollard@hud.gov* for a copy of the proposed forms or other available information. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

FOR FURTHER INFORMATION CONTACT: Harry Messner, Program Analyst, Program Administration Office: Department of Housing and Urban Development, 451 7th Street SW., Washington, DC 20410; email *harry.messner@hud.gov* or telephone 202–402–2626. This is not a toll-free number. Persons with hearing or speech impairments may access this number through TTY by calling the toll-free Federal Relay Service at (800) 877–8339.

Copies of available documents submitted to OMB may be obtained from Ms. Pollard.

SUPPLEMENTARY INFORMATION: This notice informs the public that HUD is seeking approval from OMB for the information collection described in Section A.

A. Overview of Information Collection

Title of Information Collection: Uniform Physical Standards & Physical Inspection Requirements.

OMB Approval Number: 2502–0369.

Type of Request: Extension of currently approved collection.

Form Number: N/A.

Description of the need for the information and proposed use: All multifamily properties owned by HUD or with HUD-insured mortgages must be inspected regularly to ensure that they are maintained in a condition that is decent, safe, sanitary, and in good repairs.

Respondents: Affected public.

Estimated Number of Respondents: 12,125.

Estimated Number of Responses: 12,125.

Frequency of Response: Annual.

Average Hours per Response: 6.

Total Estimated Burden: 26,706.

B. Solicitation of Public Comment

This notice is soliciting comments from members of the public and affected parties concerning the collection of information described in Section A on the following:

(1) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(2) The accuracy of the agency's estimate of the burden of the proposed collection of information;

(3) Ways to enhance the quality, utility, and clarity of the information to be collected; and

(4) Ways to minimize the burden of the collection of information on those who are to respond; including through the use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses.

HUD encourages interested parties to submit comment in response to these questions.

Authority: Section 3507 of the Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35.

Dated: August 9, 2016.

Janet M. Golrick,

Associate General Deputy Assistant Secretary for Housing—Associate Deputy Federal Housing Commissioner.

[FR Doc. 2016–19637 Filed 8–16–16; 8:45 am]

BILLING CODE 4210–67–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–567 (Advisory Opinion Proceeding)]

Certain Foam Footwear; Institution of an Advisory Opinion Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to institute an advisory opinion proceeding in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Clint Gerdine, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 708–2310. Copies of non-confidential documents filed in connection with this investigation are or will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. General information concerning the Commission may also be obtained by accessing its Internet server at *http://www.usitc.gov.* The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.* Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission instituted this investigation on May 11, 2006, based on a complaint, as amended, filed by Crocs, Inc. ("Crocs") of Niwot, Colorado. 71 FR 27514–15 (May 11, 2006). The complaint alleged, *inter alia,* violations of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain foam footwear, by reason of infringement of claims 1–2 of U.S. Patent No. 6,993,858 ("the '858 patent") and U.S. Patent No. D517,789 ("the '789 patent"). The notice of investigation named several respondents including Double Diamond Distribution Ltd. ("Double Diamond") of Saskatoon, Canada.

On July 25, 2008, the Commission issued its final determination finding no violation of section 337 based on non-infringement and non-satisfaction of the technical prong of the domestic industry requirement with respect to the '789 patent, and invalidity of the '858 patent as obvious under 35 U.S.C. 103. 73 FR 45073–74 (Aug. 1, 2008). On July 15, 2011, after an appeal to the U.S. Court of Appeals for the Federal Circuit and subsequent remand vacating the Commission's previous finding of no violation, the Commission found a violation of section 337 based on infringement of the asserted claims of the patents and issued a general exclusion order and, *inter alia,* a cease and desist order directed against Double Diamond. 76 FR 43723–24 (July 21, 2011).

On July 12, 2016, Double Diamond and U.S.A. Dawgs, Inc. ("USA Dawgs") of Las Vegas, Nevada (collectively, the "requesters") petitioned for institution of an advisory opinion proceeding as to whether their Fleece Dawgs footwear is covered by the general exclusion order or cease and desist order directed against Double Diamond. No responses were filed.

The Commission has determined that requesters' petition complies with the requirements for institution of an advisory opinion proceeding under Commission Rule 210.79 to determine whether their Fleece Dawgs footwear infringes the '789 patent or claims 1 or 2 of the '858 patent. Accordingly, the Commission has determined to institute an advisory opinion proceeding and refer requesters' petition to the Office of Unfair Import Investigations ("OUII"). The parties will furnish OUII with information as requested, and OUII shall investigate and issue a report to the Commission within ninety (90) days of the date of publication of this notice in the **Federal Register**. The Commission will issue an advisory opinion within 45 days of receipt of OUII's written report. The following entities are named as parties to the proceeding: (1) Crocs; (2) Double Diamond; and (3) USA Dawgs.

The authority for the Commission's determination is contained in sections 335 and 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1335, 1337), and in Part 210 of the Commission's Rules of Practice and Procedure (19 CFR part 210).

By Order of the Commission.

Issued: August 11, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19561 Filed 8–16–16; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

Notice of Receipt of Complaint; Solicitation of Comments Relating to the Public Interest

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has received a complaint entitled *Certain Athletic Footwear, DN 3166;* the Commission is soliciting comments on any public interest issues raised by the complaint or complainant's filing under section 210.8(b) of the Commission's Rules of Practice and Procedure (19 CFR 210.8(b)).

FOR FURTHER INFORMATION CONTACT: Lisa R. Barton, Secretary to the Commission, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000. The public version of the complaint can be accessed on the Commission's Electronic Document Information System (EDIS) at EDIS,[1] and will be available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone (202) 205–2000.

General information concerning the Commission may also be obtained by accessing its Internet server at United States International Trade Commission (USITC) at USITC.[2] The public record for this investigation may be viewed on the Commission's Electronic Document Information System (EDIS) at EDIS.[3] Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on (202) 205–1810.

SUPPLEMENTARY INFORMATION: The Commission has received a complaint and a submission pursuant to section 210.8(b) of the Commission's Rules of Practice and Procedure filed on behalf of Reebok International Ltd. and Reebok International Limited on August 10, 2016. The complaint alleges violations of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain athletic footwear. The complaint names as respondents TRB Acquisitions LLC of New York, NY; RBX Active 01 LLC of New York, NY; RBX DIRECT LLC of New York, NY; RBX.COM LLC of New York, NY; and Elite Performance Footwear, LLC of New York, NY. The complainant requests that the Commission issue a limited exclusion order, cease and desist orders and impose a bond upon respondents' alleged infringing articles during the 60-day Presidential review period pursuant to 19 U.S.C. 1337(j).

Proposed respondents, other interested parties, and members of the public are invited to file comments, not to exceed five (5) pages in length, inclusive of attachments, on any public interest issues raised by the complaint or section 210.8(b) filing. Comments should address whether issuance of the relief specifically requested by the complainant in this investigation would affect the public health and welfare in the United States, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, or United States consumers.

In particular, the Commission is interested in comments that:

(i) Explain how the articles potentially subject to the requested remedial orders are used in the United States;

(ii) identify any public health, safety, or welfare concerns in the United States relating to the requested remedial orders;

(iii) identify like or directly competitive articles that complainant, its licensees, or third parties make in the United States which could replace the subject articles if they were to be excluded;

(iv) indicate whether complainant, complainant's licensees, and/or third party suppliers have the capacity to replace the volume of articles potentially subject to the requested exclusion order and/or a cease and desist order within a commercially reasonable time; and

(v) explain how the requested remedial orders would impact United States consumers.

Written submissions must be filed no later than by close of business, eight calendar days after the date of publication of this notice in the **Federal Register**. There will be further opportunities for comment on the public interest after the issuance of any final initial determination in this investigation.

Persons filing written submissions must file the original document electronically on or before the deadlines stated above and submit 8 true paper copies to the Office of the Secretary by noon the next day pursuant to section 210.4(f) of the Commission's Rules of Practice and Procedure (19 CFR 210.4(f)). Submissions should refer to the docket number (''Docket No. 3166'') in a prominent place on the cover page and/or the first page. (*See* Handbook for Electronic Filing Procedures, Electronic Filing Procedures[4]). Persons with questions regarding filing should contact the Secretary (202–205–2000).

Any person desiring to submit a document to the Commission in confidence must request confidential treatment. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All such requests should be directed to the Secretary to the Commission and must include a full statement of the reasons why the Commission should grant such treatment. *See* 19 CFR 201.6. Documents for which confidential treatment by the Commission is properly sought will be treated accordingly. All information, including confidential business information and documents for which confidential treatment is properly sought, submitted to the Commission for purposes of this Investigation may be disclosed to and used: (i) By the Commission, its employees and Offices, and contract personnel (a) for developing or maintaining the records of this or a related proceeding, or (b) in internal investigations, audits, reviews, and evaluations relating to the programs, personnel, and operations of the Commission including under 5 U.S.C. Appendix 3; or (ii) by U.S. government employees and contract personnel,[5] solely for cybersecurity purposes. All nonconfidential written submissions will be available for public inspection at the Office of the Secretary and on EDIS.[6]

This action is taken under the authority of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and of sections 201.10 and 210.8(c) of the Commission's Rules of Practice and Procedure (19 CFR 201.10, 210.8(c)).

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[1] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[2] United States International Trade Commission (USITC): *http://edis.usitc.gov.*

[3] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

[4] Handbook for Electronic Filing Procedures: *http://www.usitc.gov/secretary/fed_reg_notices/rules/handbook_on_electronic_filing.pdf.*

[5] All contract personnel will sign appropriate nondisclosure agreements.

[6] Electronic Document Information System (EDIS): *http://edis.usitc.gov.*

By order of the Commission.

Issued: August 10, 2016.

Lisa R. Barton,

Secretary to the Commission.

[FR Doc. 2016–19560 Filed 8–16–16; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. 16–14]

Lawrence E. Stewart, M.D.; Decision and Order

On June 1, 2016, Administrative Law Judge (ALJ) Charles Wm. Dorman issued the attached Recommended Decision. Therein, the ALJ found that on multiple occasions, Respondent issued prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose for schedule II controlled substances such as Norco 10/325mg (hydrocodone/acetaminophen) and Hycodan (hydrocodone/homatropine cough syrup),[1] the schedule III controlled substance phentermine, and the schedule IV controlled substance alprazolam, in violation of 21 CFR 1306.04(a). See R.D. at 34–60.[2]

More specifically, the evidence showed that Respondent prescribed the controlled substances to his girlfriend knowing that she was seeking the drugs to abuse them. The evidence also showed that while some of the prescriptions were issued in the name of Respondent's girlfriend, in multiple instances, Respondent issued prescriptions, including multiple prescriptions for Hycodan, listing his girlfriend's two children, who were then three and five years old respectively, as the patients, and that Respondent did so knowing that his girlfriend intended to use the cough syrup because she enjoyed drinking it. The evidence further showed that on multiple occasions, Respondent issued prescriptions for Norco [3] to undercover agents who posed as acquaintances of his girlfriend, knowing that the drugs would then be provided to his girlfriend and that Respondent further instructed his girlfriend as to how her purported acquaintances should present as having headaches so that he could document a reason in the their charts for having issued the prescriptions.

The ALJ also found that on multiple occasions, Respondent violated Rule 1.4 of the Mississippi State Board of Medical Licensure's Rules by failing to document in his girlfriend's chart the diagnosis or justification for issuing the prescription, as well as required information including the drug's name, the dose, strength and quantity. R.D. at 37–39 (citing Miss. Code R. § 30–17–2640:1.4; also citing *id.* § 30–17–2640:1.16; Miss. Code §§ 73–25–29(3) and (13)). The ALJ also made a similar finding with respect to four hydrocodone cough syrup prescriptions Respondent issued in the names of his girlfriend's children. R.D. at 46–47 (Rx's issued on 6/17/14, 7/23/14, 11/19/14); *id.* at 49 (Rx 11/3/14).

With respect to the phentermine prescriptions Respondent issued to his girlfriend, the ALJ found that he "completely failed to comply" with the Board's Rule 1.5 because he did not prescribe "adjunctively with caloric restriction," "never conducted and recorded an initial comprehensive evaluation" including "a thorough patient history or physical examination," and never recorded required histories, nor her height, weight, BMI, body measurements, and vital signs. R.D. 43. The ALJ also found that Respondent did not conduct a re-evaluation of his girlfriend every 30 days as required by Rule 1.5. *Id.* Finally, noting that Rule 1.5 generally requires that the patient have a BMI greater than 30 in order to justify prescribing phentermine, the ALJ observed that Respondent's girlfriend testified that she had gone from 135 to 121 pounds and that she presented at the hearing "with a slender body type." *Id.* The ALJ thus explained that "[a]fter observing [her] appearance," he found "it difficult to comprehend . . . how Respondent could have possibly believed that [she] has a high enough BMI to justify" prescribing weight-loss medication. *Id.* The ALJ thus found that Respondent violated 21 CFR 1306.04(a), the Board's Rule 1.5, and Mississippi Code sections 73–25–29(3) and (13) when he prescribed phentermine to his girlfriend. *Id.* at 44.

Based on these findings, the ALJ concluded that Respondent had engaged in "an egregious level of intentional diversion" and that the Government had satisfied its *prima facie* burden of showing that "Respondent's continued registration would be inconsistent with the public interest." R.D. at 61. Because "Respondent offered no evidence that he accepted responsibility for his misconduct or reformed his ways," the ALJ found that he "failed to rebut the Government's *prima facie* case." *Id.* The ALJ thus recommended that I revoke Respondent's registration and deny any application to renew or modify his registration. *Id.*

Respondent filed Exceptions to the ALJ's Recommended Decision. Thereafter, the ALJ forwarded the record to me for Final Agency Action.

Having considered the record in its entirety, including Respondent's Exceptions, I have decided to adopt the ALJ findings of fact, conclusions of law, and recommended Order. However, before I address Respondent's Exceptions, I deem it necessary to address the ALJ's ruling on the admissibility of the FDA package insert for Hycodan (GX 4).

On motion of Respondent's counsel, the ALJ ruled inadmissible Government Exhibit 4, which the Government represented was the FDA package insert for Hycodan.[4] Tr. 422, 427. The basis of Respondent's objection was that the exhibit contains "little more than generalizations and medical opinions" and that the ALJ's prehearing statement required the parties to disclose "the names and credentials and opinions of medical experts . . . who would be offering medical opinions in this case." *Id.* at 420. Respondent's counsel further argued that "[t]he government did not identify any expert capable of being cross-examined on any of these opinions" and that "[t]here is no reason to believe that [the Exhibit was] authored by a physician, much less do we know whether the author had credentials to offer these opinions." *Id.*

After the Government argued that the document was the FDA package insert, which is included "with every drug purchased or sold," *id.* at 422, Respondent argued that the copyright of the document was the manufacturer and that "we don't know who authored it, or what their credentials were, but it's a self-interested marketing pharmaceutical company" that is "trying to sell their [sic] medicine" and while the company has a "self-interest[] to comply with a federal regulation . . . "[i]t doesn't mean that the content is government-sanctioned." *Id.* at 422–23. Respondent thus asserted that the document was "just not reliable enough." *Id.* at 426.

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[1] Effective October 6, 2014, combination hydrocodone products including both Norco and Hycodan were transferred from schedule III to schedule II of the Controlled Substances Act. *See Schedules of Controlled Substances: Rescheduling of Hydrocodone Combination Products from Schedule III to Schedule II,* 79 FR 49661. Thus, at the time Respondent issued some of the Norco and Hycodan prescriptions, the drug was a schedule III controlled substance. This, however, has no consequence for my decision.

[2] All citations to the Recommended Decision are to the slip opinion as issued by the ALJ.

[3] The evidence also showed that at one of the undercover agent's visits, Respondent also gave her a prescription for Hycodan cough syrup.

[4] There is no dispute that the Exhibit was what the Government represented it to be—a copy of the package insert. Nor is there any dispute as to how the document was obtained.

The ALJ sustained the objection but provided no explanation as to his reason for doing so. I conclude, however, that the Exhibit was admissible. As the FDA has explained, the package insert "is part of the FDA-approved labeling," and "[t]he FDA approved label is the official description of a drug product, which includes indication (what the drug is used for); who should take it; adverse events (side effects); instructions for uses in pregnant women, children, and other populations; and safety information for the patient." *See* U.S. Food and Drug Administration, *Drugs@ FDA Instructions: Health Information,* available at *www.fda.gov/Drugs/InformationOnDrugs/ucm079450.htm* (accessed August 4, 2016). The FDA's approval of a drug label follows extensive clinical trials, including trials which examine the safety and effectiveness of a drug and are part of the process for approving the drug for marketing. *See* Food and Drug Administration, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products,* 71 FR 3922 (2006) (Final Rule) ("A prescription drug product's FDA-approved labeling (also known as 'professional labeling,' 'package insert,' 'direction circular,' or 'package circular') is a compilation of information about the product, approved by FDA, based on the agency's thorough analysis of the new drug application (NDA) . . . submitted by the applicant. This labeling contains information necessary for safe and effective use.").

Under the Food, Drug and Cosmetic Act, a drug "shall be deemed to be misbranded . . . [u]nless its labeling bears . . . such adequate warning against use . . . by children where its use may be dangerous to health." 21 U.S.C. 352(f). Moreover, introducing a misbranded drug into interstate commerce is a violation of 21 U.S.C. 331(a). Thus, there are ample incentives for drug manufacturers to provide reliable information in the package insert. Based on the foregoing, I find that there are sufficient indicia of reliability to support the admission of the document into evidence and make it a part of the record.[5] I further find that this evidence is probative on the issue of whether the Hycodan prescriptions issued by Respondent in the name of his girlfriend's children were for a legitimate medical purpose. *See, e.g., Medicine Shoppe-Jonesborough* v. *DEA,* 300 Fed. Appx. 409, 413 (6th Cir. 2008) (holding that dispensing contraindicated controlled substance is evidence of 21 CFR 1306.04(a) violation).

Notably, the Hycodan package insert's safety information includes the following warning: "The use of HYCODAN is not recommended for use in children less than 6 years of age because of the risk of fatal respiratory depression." GX 4, at 2. Notably, Respondent's girlfriend's daughter was not even five years old when he wrote the first Hycodan prescription in her name. GE 55, at 1–2. Respondent also wrote Hycodan prescriptions in the name of his girlfriend's son who was then three years old. *Id.* at 3–4; 11–12. In short, neither of the children who were listed as the patients on the Hycodan prescriptions was six years of age when Respondent wrote the prescriptions. Thus, I consider this as additional evidence which supports the conclusion that Respondent lacked a legitimate medical purpose and acted outside of the usual course of professional practice when he issued the Hycodan prescriptions in the names of his girlfriend's children. 21 CFR 1306.04(a). I now turn to Respondent's Exceptions.

Exception I—The Government Failed "to Prove Violations of State or Local Laws Sufficient to Demonstrate Danger to the Public Interest."

Respondent argues that the ALJ failed to give proper weight to the decision of Dr. Craig, the Medical Board's Executive Director, to close the Board's investigation of his prescribing practices without recommending the initiation of a formal action against his medical license. Exceptions, at 1–2. According to Respondent, the Board reviewed "all such clinical and prescription records" for his girlfriend and her children, and it "decided that there was no evidence of any breach of any medical standard of care sufficient to bring any administrative charge against [him] related to any such prescription." *Id.* at 2. He also asserts that Dr. Craig "determined that there was not even sufficient professional reason to issue [him] an informal warning as to any such prescription for pain medication." *Id.*

Respondent then argues that "[r]ather than . . . defer[] to the professional judgments made by [Dr. Craig as to] whether State laws were violated by [him], the ALJ['s] Recommendation proceeds to interpret and apply those State laws without the benefit of any medical evidence, or any medical opinion in any form, anywhere in the record of this case." *Id.* And noting the ALJ's discussion that "'DEA has not required expert testimony to establish a violation of 21 CFR 1306.04(a) in cases where a prescriber engaged in drug deals, where there were notable differences between patients' medical records and diagnoses, and where a prescriber falsified patients' charts,'" Respondent contends that the Government did not allege that he engaged in any such conduct. *Id.* at n.1.

I reject the Exception. As for the contention that Dr. Craig reviewed the medical records and prescriptions and did not find the evidence sufficient to initiate a proceeding against his license, Respondent ignores the credited testimony that the Board terminated its investigation upon the request of the Mississippi Bureau of Narcotics (MBN) after the latter informed the Board that it was conducting a criminal investigation. Tr. 60 (testimony of MBN agent); GE 3, at 2 (Board Complaint form entry dated "3–20–15" stating "MBN has asked that we hold off on doing anything to this doctor because they are working a criminal case on him").[6] A Board investigator also testified that "it's customary for [the Board] to back off [of an investigation] and let a criminal agency pursue their [sic] case" and that Dr. Craig was aware of the criminal investigation. Tr. 210.

Moreover, even then the Board's letter cautioned Respondent "that authorizing refills for Phentermine/Adipex without the benefit of a medical examination is strictly prohibited by the Board's Rules and Regulations” and specifically quoted the Board's Rule 1.5(E), which states that: “[a] patient continued on a controlled substance in schedule III, IV, V for the purpose of weight reduction or the treatment of obesity should undergo an in-person re-evaluation once every 30 days.” GE 3, at 1. Finally, as the evidence shows, subsequent to the Board's closing of its investigation, Respondent again issued multiple controlled substance prescriptions to purported acquaintances of his girlfriend knowing that the drugs would subsequently be provided to his girlfriend. Accordingly, I reject Respondent's contention that the Board's closing of its investigation reflects its “professional judgments” that Respondent acted within the bounds of accepted professional practice when he prescribed to Respondent and the undercover officers.

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[5] Hearsay evidence is admissible in administrative proceedings, provided it is relevant and material and supported by sufficient indicia of reliability. *See, e.g., Mireille Lalanne,* 78 FR 47750 (2013).

As further noted above, in opposing the admission of the package insert, Respondent represented that it contained expert opinions from unidentified persons whom he could not cross-examine and thus was being offered in violation of the ALJ's Prehearing Order. However, in its prehearing statement, the Government provided notice that it intended to offer the Exhibit and pursuant to the ALJ's Prehearing Ruling, the Government was required to provide the document to Respondent by 2 p.m. on February 12, 2016. ALJ Ex. 9, at 2. No claim is made that the Government failed to comply with the ALJ's ruling.

While Respondent asserts that he was unable to cross-examine the persons who wrote the package insert, he made no attempt to subpoena either an FDA official involved in reviewing the document or an employee from the manufacturer who was involved in preparing it. Moreover, Respondent could have sought to challenge the reliability of the document by producing evidence (whether through expert testimony or studies) disputing the package insert's statement regarding the risks of prescribing the drug to children less than six years of age. Respondent, however, produced no evidence which calls into question the reliability of the statements contained in the insert.

[6] The Board's investigation involved interviewing Respondent, as well as reviewing his girlfriend's patient file and a PMP report of her controlled substance prescriptions. GE 3, at 4–6. Notably, the Board's investigator testified that the Board did not interview Respondent's girlfriend. Tr. 196.

Under both this and his subsequent exception, Respondent argues that the ALJ's decision is unprecedented because the Government put forward no expert testimony to support the conclusion that he violated 21 CFR 1306.04(a) in issuing the various prescriptions. However, contrary to Respondent's understanding, numerous decisions of both the federal courts in criminal cases and this Agency have held that expert testimony is not necessarily required to prove that a physician acted outside of the usual course of professional practice and lacked a legitimate medical purpose in issuing a controlled substance prescription. *See United States* v. *Pellman,* 668 F.3d 918, 924 (7th Cir. 2012) (quoting *United States* v. *Armstrong,* 550 F.3d 382, 388–89 (5th Cir. 2008) (“While expert testimony may be both permissible and useful, a jury can reasonably find that a doctor prescribed controlled substances not in the usual course of professional practice or for other than a legitimate medical purpose from adequate lay witness evidence surrounding the facts and circumstances of the prescriptions.”)); *Armstrong,* 550 F.3d at 389 (“Jurors have had a wide variety of their own experiences in doctors' care over their lives, thus and expert testimony is not necessarily required for jurors to rationally conclude that seeing patients for as little as two or three minutes before prescribing powerful narcotics is not in the usual course of professional conduct.”).[7] *See also T.J. McNichol,* 77 FR 57133, 57147–49 (2012), *pet. for rev. denied,* 537 Fed. Appx. 905 (11th Cir. 2013); *Morris W. Cochran,* 77 FR 17505, 17519–20 (2011) (holding, without expert testimony, that prescriptions lacked a legitimate medical purpose where physician noted in patient medical records that patients had no pain, did not document any findings to support a diagnosis, and yet diagnosed patients as having chronic pain); *Robert F. Hunt,* 75 FR 49995, 50003 (2010) (holding, without expert testimony, that physician lacked a legitimate medical purpose based on statements made during undercover visits and falsification of chart). *See also Jack A. Danton,* 76 FR 60900, 60904 (2011).

Thus, while expert testimony is typically necessary to establish a violation of 21 CFR 1306.04(a) “ ‘where a physician ma[kes] some attempt to comply with various state medical practice standards and the adequacy of those efforts is at issue,' . . . the facts and circumstances surrounding the issuance of the prescription may nonetheless establish a violation even without expert testimony.” *McNichol,* 77 FR 57147–48 (quoting *Danton,* 76 FR at 60904 & n.13). Accordingly, in *McNichol,* the Agency found a violation proved, notwithstanding that the ALJ had rejected the testimony of the Government's Expert, because while the physician had gone through the motions of a physical exam, the physician's “comments manifest[ed] that he knew that [the patient] was an abuser of controlled substances.” *Id.* at 57148. *See also Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (“[T]he prescription requirement . . . ensures patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses.”) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

Here, as the ALJ found, Respondent issued multiple prescriptions to his girlfriend while failing to document the performance of a physical exam, as well as findings and diagnoses that would support the issuance of the prescriptions. Moreover, with respect to the hydrocodone cough syrup prescriptions Respondent issued to his girlfriend which listed her children as the patients, the ALJ credited her testimony that she told Respondent that she wanted the big bottle of hydrocodone cough syrup and he “knew I would drink it too.” R.D. 7; 11 (citing Tr. 216, 251–52, 268, 273); *see also* Tr. 298 (girlfriend's testimony that the Norco prescriptions were “not for a headache” but were “[j]ust for fun”). Likewise, with respect to the prescriptions Respondent provided in March and April 2015 to his girlfriend's purported acquaintances, the undercover recordings clearly establish that Respondent knew that the acquaintances were not seeking the prescriptions to treat legitimate medical conditions but to provide the drugs to his girlfriend. Given the evidence that clearly shows that Respondent issued the prescriptions to support his girlfriend's abuse of controlled substances, the Government was not required to put forward expert testimony to prove its case.

Exception II—The Government “Fail[ed] to Prove ‘Past Experience in the Distribution of Controlled Substances.' ”

Respondent further argues that the ALJ erred when he refused “to allow Respondent to seek clinical evidence about [his girlfriend's] medical history through third-party document subpoenas.” Exceptions, at 2. Prior to the hearing, Respondent requested that the ALJ issue eight subpoenas to health care providers for their medical records “which reflect, relate to, or explain the clinical or medical basis for prescribing” controlled substances (primarily hydrocodone with acetaminophen) to his girlfriend. *See, e.g.,* ALJ Ex. 13, at 6.

In seeking the subpoenas, Respondent maintained that “[i]n order for the truth about [his girlfriend's] medical condition and needs to be revealed . . . the clinical findings and judgment of all such health care providers should be available to the Court in order to allow a comparison between Dr. Stewart's judgment and the judgments of a substantial number of other health care professionals in the same community.” ALJ Ex. 13, at 3. On the various subpoenas, Respondent explained that because one of the Government's Exhibits (the PMP report, GE 49) shows that the other health care providers had also issued hydrocodone prescriptions to his girlfriend, “[t]he presumed legitimacy of the particular clinical findings which caused [the] other health care professionals in the same community to prescribe the same medication to [her] could be strongly probative of the medical inaccuracy of the . . . core allegations against” him. *See, e.g.,* GE 13, at 6.

The Government opposed the issuance of the subpoenas. It argued that the information Respondent sought was irrelevant because the only allegations it raised as to the unlawful prescribing of hydrocodone with acetaminophen to his girlfriend involved the four Norco prescriptions which were identified in paragraph 4 of the Show Cause Order.[8] ALJ Ex. 14, at 2–3. The Government also argued that "[i]n each of those instances," it was "alleg[ing] that Respondent prescribed to [her] either without conducting any examination of her or without noting those prescriptions in her chart." *Id.* at 3. And it further argued that none of the records would address the "actual charges against" Respondent. *Id.*

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[7] *See also United States* v. *Word,* 806 F.2d 658, 663 (6th Cir. 1986); *United States* v. *Larson,* 507 F.2d 385, 387 (9th Cir. 1974); *United States* v. *Bartee,* 479 F.2d 484, 488–89 (10th Cir. 1973); *State* v. *Moody,* 393 So.2d 1212, 1215 (La. 1981).

The ALJ agreed with the Government and denied Respondent's request. ALJ Ex. 16. The ALJ explained that having reviewed the allegations of the Show Cause Order, he agreed with "the Government's assessment that the question of whether [Respondent' girlfriend] needed a particular medication is not an issue before me." *Id.* at 1. And noting that "Respondent has not produced a summary of [his] expected testimony," the ALJ then reasoned that "there is no information in the record that the Respondent based his decision to prescribe a particular medication to [his girlfriend] based upon his knowledge of what some other treating physician had prescribed for" her. *Id.* at 1–2. Concluding that the information sought by Respondent was irrelevant, the ALJ denied the request. *Id.* at 2.

I conclude that the ALJ properly denied Respondent's request. I do not, however, read the Government's Opposition as expressing the position that his girlfriend's need for the Norco prescriptions was not at issue.

While the Government alleged that these particular prescriptions were unlawful because: (1) Respondent did not "conduct[] an examination of" of his girlfriend or "document[] such in her file," or (2) Respondent did not note the prescriptions in her chart and thus violated the Board's Rules 1.4, 1.11(b) and 1.16, the Government also cited 21 CFR 1306.04(a)). Because "[a] prescription for a controlled substance to be effective must be issued for a legitimate medical purpose," 21 CFR 1306.04(a), a patient's need for the drug is invariably at issue when a violation of this provision is alleged. *See also* Miss. Code R. § 30–17–2640:1.4 ("No physician shall prescribe, administer or dispense any controlled substance . . . without a good faith prior examination and medical indication therefore."). Indeed, assessing whether a patient needs a controlled substance to treat a medical condition is the reason why the usual course of professional practice generally requires that a physician take a detailed history and conduct an appropriate examination of the patient to make a proper diagnosis and treatment plan.[9] *See id.*

I nonetheless agree with the ALJ's conclusion that the information sought by the subpoenas was irrelevant. Notably, Respondent made no proffer that he had obtained and reviewed the records maintained by these other providers and had based his decisions to prescribe hydrocodone to his girlfriend on those records. Nor did Respondent proffer that he was acting as a covering physician for any of these other physicians (or any other authorized prescriber) when he prescribed the hydrocodone to his girlfriend.

Respondent further contends that the prescriptions issued by the other providers "strongly support a conclusion that [his] own prescriptions for [h]ydrocodone for use by [his girlfriend] were within the bounds of the medical standard of care practiced in that community." Exceptions, at 4. However, were it the case that Respondent's prescribing of hydrocodone was within the bounds of professional practice, he could have put on an expert to testify as such.[10] Yet Respondent chose not do so.

Respondent also contends that the evidence is insufficient to show that the hydrocodone prescriptions lacked a legitimate medical purpose because "it is clear that during the months relevant to this case [his girlfriend] was in fact suffering from a chronic migraine condition and associated headache pain, and that [he] was treating her for that condition." Exceptions, at 3. Respondent points to the testimony of his girlfriend that she was hospitalized for migraines "[t]hree times prior to the beginning of his treatment of her in February 2014, and a fourth time during that treatment in August of 2014." *Id.* He further maintains that his charts "specified that she complained of, and in fact suffered from, a chronic migraine condition." *Id.*

It is true that in two of the visit notes for his girlfriend (April 21 and Sept. 2, 2014), Respondent listed Maxalt, a non-controlled drug, and Norco (hydrocodone with acetaminophen), as the drugs he prescribed to her for this condition. GE 2, at 12. Yet prior to Respondent's issuance of the first Norco prescription to her, she had "asked him to write the big bottle" of hydrocodone cough syrup "so that [she] could have some too" and "told him I like to drink it" because she "like[d] the way it made [her] feel." Tr. 251–52; 273. Thus, Respondent already knew that his girlfriend was a drug abuser.[11]

The evidence also shows that Respondent told his girlfriend that taking hydrocodone could itself "cause migraines." *Id.* at 283; *see also id.* at 299. Respondent's girlfriend testified that he told her that taking hydrocodone "would not help" her migraines. *Id.* at 300. She further testified that "[t]he hydrocodone was not for a headache," but for "[e]xtracurricular activities," *i.e.,*

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[8] The Show Cause Order alleged that the prescriptions were issued on May 22, June 17, September 11, and October 29, 2014. ALJ Ex. 1, at 2.

[9] As Rule 1.4 further states:

> Standards of proper medical practice require that, upon any encounter with a patient, in order to establish proper diagnosis and regimen of treatment, a physician must take three steps: (a) Take and record an appropriate medical history, (b) carry out an appropriate physical examination, and (c) record the results. The observance of these principles as a function of the "course of legitimate professional practice" is particularly of importance in cases in which controlled substances are to play a part in the course of treatment. It is the responsibility of the physician to dispense, prescribe or administer such drugs with proper regard for the actual and potential dangers.

Miss. Code R. § 30–17–2640:1.4.

[10] Respondent initially proposed to call a physician and professor from the University of Mississippi Medical Center who would testify that the prescriptions he issued "were for legitimate medical purposes" and "were in the usual course of and consistent with [his] own standard professional practices [and] were consistent with the standard of care in the medical community in which they lived." ALJ Ex. 17, at 2–3. While the Government moved to exclude the proffered testimony, the ALJ denied the Government's motion and specifically ruled that the expert could testify to the above subjects. ALJ Ex. 28, 3–4. Respondent did not, however, call this witness.

Of further note, even if Respondent had put on testimony that the prescriptions were "consistent with [his] own standard professional practices," that testimony would have been unavailing because the standard of professional practice is not defined by a physician's subjective belief as to the propriety of his practices but on the application of the standards of practice in the State where he practices. *United States* v. *Tobin,* 676 F.3d 1264, 1290 (11th Cir. 2012). For similar reasons, evidence as to the standard of care in the medical community in which Respondent lived would also be unavailing.

[11] Respondent points to the testimony of his girlfriend that she never told him that she was addicted to hydrocodone, dependent on the drug, or taking it "for no reason." Exceptions, at 3. As discussed above, Respondent's girlfriend subsequently clarified that she took the Norco "just for fun." Tr. 298.

To the extent Respondent believes that his misconduct in writing the Norco prescriptions should be excused because his girlfriend did not tell him why she was taking the Norco, the evidence is clear that she had previously asked him to prescribe the big bottle of cough syrup so that she "could have some too" and had told him that she "like[d] to drink it" because of "the way it made [her] feel." Thus, Respondent clearly knew that his girlfriend was a drug abuser at the time he wrote her the first Norco prescription.

"just for fun." *Id.* at 298. Moreover, Respondent issued the first of the Norco prescriptions to her without even taking a history and conducting a physical examination of her. GE 2, at 12; *see* Miss. Code R. § 30–17–2640:1.4. He also failed to document several of the hydrocodone prescriptions in his girlfriend's chart.[12] *Compare* GE 2, at 12, *with* GE 3, at 9–10. Thus, the evidence strongly supports the conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he prescribed Norco to his girlfriend. 21 CFR 1306.04(a).

Respondent also appears to argue that the alprazolam prescription he issued to his girlfriend was not unlawful because she suffered from anxiety and he referred her to a psychiatrist who had prescribed the drug to her. Exceptions, at 4. While Respondent acknowledges that he did not "diagnose [her] himself as to anxiety," he argues that he issued the prescription "in reliance on that psychiatrist's independent clinical judgment" and gave her a refill so that she could "avoid[] further one-hour trips to the psychiatrist to obtain a refill." *Id.*

I am not persuaded. Notably, the psychiatrist prescribed only a seven-day supply of alprazolam extended release in the .5 mg dosage. GE 49, at 1. Respondent, however, prescribed a stronger dosage of alprazolam and greater quantity, providing her with a prescription for 40 tablets of the 1mg immediate release dosage form, with a refill for an additional 40 tablets. *Id.* This was not a refill of the psychiatrist's prescription at all, but a substantially different and stronger prescription. Yet the medical record contains no evidence that Respondent coordinated his prescribing with the psychiatrist. As for Respondent's explanation that he wrote the prescription so that his girlfriend would not have to make the one-hour trip to obtain a refill, this begs the question as to why the psychiatrist would not be willing to call in a refill. I thus reject Respondent's Exception to the extent it challenges the ALJ's findings as to the alprazolam prescription.

As for the phentermine prescriptions, Respondent again invokes Dr. Craig's letter in which he stated that the Board was closing its investigation while cautioning Respondent about the need to conduct an in-person re-evaluation every 30 days. Exceptions, at 4. Respondent revisits his argument that Dr. Craig "determined that there was no sufficient medical basis for alleging any violation . . . of any medical standard in Mississippi." *Id.* However, as previously explained, the Board terminated its investigation because Respondent was the subject of a criminal investigation. Moreover, the ALJ thoroughly explained the basis for his conclusion that Respondent acted outside of the usual course of professional practice and lacked a legitimate medical purpose when he issued the phentermine prescriptions to his girlfriend.[13]

Finally, Respondent argues that "[t]he DEA, through the CI [his girlfriend], effectively caused [him] to engage in conduct, which, according to the record . . . he apparently had never engaged in on any other occasion." Exceptions, at 5. Continuing, Respondent argues that his "conduct, in issuing prescriptions for pain medications to third parties in an effort to provide the CI with continuing relief from her migraine conditions, arose from the peculiar combination of his personal relationship and familiarity with the CI and the CI's insistence that her 'friends' were seeking medication for" her use. *Id.* Respondent thus maintains that this "peculiar circumstance . . . provides no significant medical or other evidence sufficient to justify any conclusion that [his] conduct . . . poses, or is likely to pose in the future, any danger to the public health or safety." *Id.*

I disagree. To the extent Respondent's argument sounds in the entrapment defense, I reject it as there is ample evidence that he was predisposed to issue the unlawful prescriptions given the multiple unlawful prescriptions he wrote for his girlfriend in 2014, prior to the involvement of the MBN and DEA. *See United States* v. *Sumlin,* 271 F.3d 274 (D.C. Cir. 2001). As for the assertion that he wrote the prescriptions to the undercover agents to provide his girlfriend "with continuing relief from her migraine conditions," this is simply counterfactual as the record abounds with evidence that Respondent knew she was seeking the drugs to abuse them. Tr. 345; GE15; 16; GE 17, at 2–4, 6–8; GE 18, at 3. I therefore reject Respondent's contention that there is no "significant medical or other evidence" to support the conclusion that he poses a danger to public health and safety.[14] Exceptions, at 5. To the contrary, the evidence shows that on multiple occasions, Respondent issued prescriptions outside of the usual course of professional practices and which lacked a legitimate medical purpose to feed his girlfriend's abuse of controlled substances. This conduct amply supports the conclusion that he has committed such as acts as to render his registration "inconsistent with the public interest." 21 U.S.C. 824(a)(4).

Exception III—The ALJ Violated Respondent's Fifth Amendment Rights When He Denied His Request To Delay the Hearing Until the End of His Criminal Trial

Respondent's final contention is that the ALJ violated his Fifth Amendment privilege against self-incrimination when he denied his request to reschedule the hearing until after his criminal trial concluded. Exceptions, at 5–6. Notably, the Government did not call Respondent to testify and the ALJ declined to draw an adverse inference from his failure to testify on his own behalf even though doing so would have been warranted. *See Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 326 (9th Cir. 1995) ("Not only is it permissible to conduct a civil proceeding at the same time as a related criminal proceeding, even if that necessitates invocation of the Fifth Amendment privilege, but it is even permissible for the trier of fact to draw adverse inferences from the invocation of the Fifth Amendment in a civil proceeding.") (citing *Baxter* v. *Palmigiano,* 425 U.S. 308, 318 (1976)).

Here, Respondent does not contend that the need to preserve his Fifth Amendment privilege prevented him from providing testimony refuting the allegations that he unlawfully prescribed various controlled substances to his girlfriend and the undercover officers. Rather, he argues that "[b]ecause he desired understandably to preserve and not to waive his Fifth Amendment privileges with respect to his criminal trial, [he] was prohibited from 'rebutting' any *prima facie* Government case through his own hearing testimony, which was the only practical way he had to 'accept responsibility' or to affirm that he 'will not engage in future misconduct.'" *Id.* at 6.

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[12] Indeed, Respondent wrote the first Norco prescription for her on February 21, 2014. The note in her patient file simply states: "2–21–14 Hc 7.5/325 (#40, 1)—may be picked up at desk." GE 2, at 12. Thus, Respondent issued the prescription without taking a history of his girlfriend's migraines and without conducting a physical exam.

[13] Respondent points to the evidence that on March 27, 2015, he declined to prescribe weight loss medication to one of the undercover agents. Exceptions, at 4 (citing GE 10, at 1–2). However, several weeks earlier, Respondent had been visited by a State Board Investigator who had told him that his documentation for the phentermine prescriptions that he issued to his girlfriend was inadequate and he may have already received the letter from Dr. Craig by the date of the first undercover visit. In any event, while Respondent may have taken to heart the warning he received from Dr. Craig regarding the prescribing of weight loss medications, this obviously had no impact on his prescribing of narcotics, as evidenced by his prescribing of Norco and Hycodan to the undercover agents.

[14] In arguing that he does not "pose . . . any danger to public health or safety," Respondent cites 21 U.S.C. 823(e), the provision which governs the registration of distributors of schedule III through V controlled substances and not practitioners, who are registered under section 823(f). However, to the extent Respondent argues that the Government is required to put forward such proof in seeking the revocation of his registration, the Government is not required to do so even though one of the section 823(f) factors is "such other conduct which may threaten the public health and safety." 21 U.S.C. 823(f). While this factor encompasses conduct which is not otherwise embraced by the other section 823(f) factors, it is indisputable that issuing prescriptions to feed a person's drug abuse is conduct which threatens public health and safety.

I reject Respondent's contention. *See Grider Drug 1 & 2,* 77 FR 44069, 44104 (2012). In *Grider,* the respondents argued that the Agency should reject an ALJ's conclusions that the pharmacies had failed to rebut the Government's *prima facie* case because their owner, who was under indictment in two state criminal cases, did not testify and thus offered no evidence to show that he had accepted responsibility and implemented corrective measures. Invoking *SEC* v. *Dresser Industries, Inc.,* 628 F.2d 1368, 1375–76 (D.C. Cir.1980), the *Grider* respondents further argued that because their owner was under indictment, the ALJ should have stayed the proceeding until the state criminal cases were concluded so as not to "undermine the party's Fifth Amendment privilege against self-incrimination." 77 FR at 44104.

The Agency rejected Grider's arguments. As the Agency explained, "'as a general matter, due process is not infringed merely because an accused person is subjected, without his consent, to an administrative hearing concerning matters involved in a pending criminal proceeding.'" *Id.* (quoting 628 F.2d at 1376 n.21). As *Dresser Industries* noted, "[t]he civil and regulatory laws of the United States frequently overlap with the criminal laws creating the possibility of parallel [administrative] and criminal proceedings, either successive or simultaneous" and that "[i]n the absence of substantial prejudice to the rights of the parties involved, such parallel proceedings are unobjectionable." 628 F.2d at 1374. Thus, in *Dresser Industries,* the D.C. Circuit observed that "[t]he Constitution . . . does not ordinarily require a stay of civil proceedings pending the outcome of criminal proceedings." *Id.* at 1375.

To be sure, in *Dresser Industries,* the D.C Circuit further explained that "the strongest case for deferring civil proceedings is where a party under indictment for a serious offense is required to defend a civil or administrative action involving the same matter." *Id.* However, the court further explained that the potential harm to a party's Fifth Amendment privilege is just one of the factors to be considered in determining whether to stay the noncriminal proceeding. *Id.* at 1376. Continuing, the court explained that "[i]f delay of the noncriminal proceedings *would not seriously injure the public interest,* a court may be justified in deferring it." *Id.* (emphasis added). That decision is, however, committed to the discretion of the trial court. *See, e.g., Keating,* 45 F.3d at 325 (setting forth multiple factors).

Here, I find no reason to conclude that the ALJ abused his discretion when he declined to continue the proceeding until the conclusion of Respondent's criminal trial. Notably, in his request for a continuance, Respondent provided no information to the ALJ as to when that trial would commence.[15] That trial—and a subsequent appeal were Respondent convicted of the charges—could go on for several years. The ALJ was not required to withhold conducting the hearing while Respondent litigates in other forums. *See* 45 F.3d at 325 (noting that "convenience of the court in the management of its cases" is a factor). So too, the Government has a strong interest in proceeding expeditiously with this litigation, and indeed, under the Constitution, the Agency has an obligation to provide prompt post-deprivation process where the Government immediately suspends a registration. *Id.; see also Barry* v. *Barchi,* 443 U.S. 56, 64 (1979).

As for the burden on Respondent, it is true that courts have held that the prejudice to a respondent's Fifth Amendment privilege may be substantial where there are parallel administrative and criminal proceedings. *Keating,* 45 F.3d at 326. However, while "the extent to which the defendant's Fifth Amendment rights are implicated is a significant factor . . . to consider . . . it is only one consideration to be weighed against others." *Id.* (citation omitted).

Notably, Respondent was not otherwise foreclosed from putting on a defense. Indeed, in its pre-hearing statement, Respondent proposed to call an expert witness who would testify that the prescriptions were lawfully issued but ultimately chose not to call this witness. Notably, in his Exceptions, Respondent does not maintain that because he invoked the privilege, he was precluded from refuting the factual basis of the allegations.

Instead, Respondent now contends that my consideration of the ALJ's recommendation "should await the disposition of the criminal case . . . following which he should be given an opportunity promptly and succinctly to tell his side of the story and express his complete remorse." Exceptions, at 6. However, as discussed above, in his Exceptions, Respondent continues to dispute the allegations (as well as the ALJ's factual findings and legal conclusions) that he issued prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose for each of the different drugs (*i.e.,* the hydrocodone cough syrup, the Norco tablets, the alprazolam, and the phentermine). Thus, his argument begs the question of which allegations he now would admit to.

The Fifth Amendment privilege is not "a sword whereby a claimant asserting the privilege [is] freed from adducing proof in support of a burden which would otherwise have been his." *United States* v. *Rylander,* 460 U.S. 752, 758 (1983). *See also MacKay* v. *DEA,* 664 F.3d 808, 820 (10th Cir. 2011) (quoting *Keating* v. *Office of Thrift Supervision,* 45 F.3d 322, 326 (9th Cir. 1995)). Indeed, the misconduct established on this record is so egregious and occurred over such a lengthy period, that even were I to remand to allow Respondent to express his "complete remorse" and the ALJ was to find this credible, I would still find his registration to be inconsistent with the public interest. *See Hatem M. Attaya,* 81 FR 8221, 8244 (2016); *Fred Samimi,* 79 FR 18698, 18714 (2014) (denying applications noting that notwithstanding ALJ's finding that physician "credibly accept responsibility for his misconduct, this is a case where actions speak louder than words"). Thus, I find that Respondent has failed to establish that the ALJ abused his discretion when he denied Respondent's request to continue the proceeding until his criminal trial concluded.[16]

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[15] In opposing the request, the Government noted that Respondent had also sought a continuance of the criminal case. ALJ Ex. 6, at 1 n.1.

[16] It is, of course, commonplace that matters involving DEA registrants will lead to both a revocation proceeding and a criminal investigation and subsequent charges at either the federal or state level. However, the very purpose of a proceeding brought under 21 U.S.C. 823(f) and 824(a)(4) is to protect the public interest, and, in the Controlled Substances Act, Congress directed that these "proceedings shall be independent of, and not in lieu of, criminal prosecutions or other proceedings under this subchapter." Thus, I conclude that the fifth *Keating* factor ("the interest of the public in the pending . . . litigation") also supports the ALJ's denial of Respondent's stay request.

Continued

Accordingly, I reject Respondent's third exception and will adopt the ALJ's recommended sanction of revocation.

ORDER

Pursuant to the authority vested in me by 21 U.S.C. 824(a) and 823(f), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration AS2286311 issued to Lawrence E. Stewart, M.D., be, and it hereby is, revoked. I further order that any application of Lawrence E. Stewart, M.D., to renew or modify the above registration, or for any additional registration be, and it hereby is, denied. This Order is effectively immediately.[17]

Dated: August 9, 2016.

Chuck Rosenberg,

Acting Administrator.

Paul A. Dean, Esq. for the Government.

J. Brad Pigott, Esq. for the Respondent.

RECOMMENDED RULINGS, FINDINGS OF FACT, CONCLUSIONS OF LAW, AND DECISION

Administrative Law Judge Charles Wm. Dorman. On December 9, 2015, the Drug Enforcement Administration ("DEA" or "Government") served Lawrence E. Stewart, M.D. ("Respondent"), with an Order to Show Cause and Immediate Suspension of Registration ("OSC/ISO"), which immediately suspended the Respondent's DEA Certificate of Registration ("COR"), Number AS2286311. Administrative Law Judge Exhibit ("ALJ-") 1–2. The Respondent's COR has remained suspended throughout these proceedings. In response to the OSC/ISO, the Respondent requested a hearing before an Administrative Law Judge. ALJ–3. That hearing was held in New Orleans, Louisiana on March 22 and 23, 2016. The issue currently before the Administrator is whether the Respondent's COR should be revoked, and applications for renewal or modification denied, because continued registration would be inconsistent with the public interest under 21 U.S.C. 823(f) and 824(a)(4). The following recommendations are based on my consideration of the entire administrative record, including all of the testimony, admitted exhibits, and the oral and written arguments of counsel.

ALLEGATIONS

1. From February 2014 to May 2015, the Respondent prescribed controlled substances, including hydrocodone and alprazolam, to a confidential informant ("CI")[1] without conducting and/or documenting a physical examination, and without recording the controlled substance prescriptions in CI's chart, in violation of Mississippi Medical Board Administrative Rules Part 2640, Chapter 1, Rules 1.4, 1.11(b), and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a). ALJ–1, at 2.

2. On four occasions, the Respondent prescribed phentermine to CI without adequate documentation, in violation of Mississippi Medical Board Administrative Rules Part 2640, Chapter 1, Rule 1.5, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a). ALJ–1, at 3.

3. From February 7, 2014 to November 19, 2014, the Respondent prescribed hydrocodone products to CI's children[2] without conducting examinations of them, and for CI's personal use, in violation of Mississippi Medical Board Administrative Rules Part 2640, Chapter 1, Rules 1.4, 1.10, 1.11(b), and 1.16, and Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) and 1306.05(a). ALJ–1, at 2–3. The Respondent prescribed hydrocodone-homatropine syrup to these children, who were under the age of six. ALJ–1, at 3. Hydrocodone-homatropine syrup is not recommended for children under the age of six because of a risk of death. ALJ–1, at 3. The Respondent also prescribed adult dosages of hydrocodone-homatropine to these children, even though the recommended dosage for children ages six to eleven is half of the adult dosage. ALJ–1, at 2–3.

4. On five occasions between March and October 2015, the Respondent prescribed controlled substances to undercover agents when he knew or should have known that the agents' prescription requests were fraudulent, in violation of 21 U.S.C. 841(a) and 842(a), and 21 CFR § 1306.04(a). ALJ–1, at 3. In total, the Respondent wrote seven prescriptions on five occasions to undercover agents, for a total of 190 dosage units of hydrocodone tablets and 72 dosage units of hydrocodone syrup. ALJ–1, at 11. On at least four of those occasions, the Respondent knew that CI would receive a portion of the prescribed controlled substances. ALJ–1, at 3–4. The Respondent also knew that CI had attempted to commit suicide using controlled substances that the Respondent had prescribed to her. ALJ–1, at 3–4.

5. From February 2014 to October 2015, the Respondent unlawfully prescribed controlled substances in violation of 21 U.S.C. 841(a) and 842(a). ALJ–1, at 2. Specifically, the Respondent prescribed controlled substances when he knew or should have known that the prescriptions were not for legitimate medical purposes and were not made in the usual course of professional practice, in violation of 21 CFR § 1306.04(a) and Mississippi Code §§ 41–29–137(a)(1) and 41–29–141(1). ALJ–1, at 2.

6. On September 2, 2014, the Respondent prescribed meperidine to CI. ALJ–1, at 3. The Respondent was the only practitioner to prescribe meperidine to CI. ALJ–1, at 3. CI used meperidine to attempt to commit suicide in December 2014. ALJ–1, at 3.

STIPULATIONS OF FACT[3]

The Government and the Respondent stipulated to the following facts:

1. Respondent is registered with the DEA as a practitioner to handle controlled substances in Schedules II–V under DEA COR AS2286311 at 405 Marion Avenue, P.O. Box 666, McComb, Mississippi 39648–2709.

2. DEA COR AS2286311 will expire by its terms on February 28, 2018.

3. Respondent is presently licensed in Mississippi as a medical doctor (M.D.) with Medical License 11503.

4. CI is the mother of Kid 1 and Kid 2.

5. Hydrocodone-Acetaminophen 10–325 (Norco), Hydrocodone-Acetaminophen 7.5–325 (Norco), Hydrocodone-Acetaminophen 5–325 (Norco), and Hydrocodone-Homatropine Syrup (Hycodan) are all classified as Hydrocodone Combination Products.

6. Hydrocodone Combination Products are classified by DEA as Schedule II Controlled Substances and have been so classified since October 6, 2014. Before October 6, 2014, Hydrocodone Combination Products were classified by DEA as Schedule III Controlled Substances.

7. Alprazolam is classified by DEA as a Schedule IV Controlled Substance.

As for the fourth *Keating* factor, "the interests of persons not parties to the [administrative] litigation," 45 F.3d at 326, Respondent puts forward no argument as to why this factor supports the requested stay or a remand at this juncture.

[17] For the same reasons that led me to immediately suspend Respondent's registration, I find that the public interest necessitates that this Order be effective immediately. *See* 21 CFR 1316.67.

[1] The Prehearing Ruling and Protective Order directed that the confidential informant would be referred to as "CI." ALJ–9, at 5. Accordingly, in this Recommended Decision, the confidential informant will be referred to as "CI."

[2] The Prehearing Ruling and Protective Order directed that CI's children would be referred to as "Kid 1" and "Kid 2." ALJ–9, at 5. Accordingly, in this Recommended Decision, CI's son will be referred to as "Kid 1," and CI's daughter will be referred to as "Kid 2."

[3] *See* ALJ–9, 20; Tr. 9.

8. Phentermine (Adipex) is classified by DEA as a Schedule IV Controlled Substance.

9. Meperidine (Demerol) is classified by DEA as a Schedule II Controlled Substance.

WITNESSES

The Government presented its case through the testimony of nine[4] witnesses. First, the Government called Kendrick Lewis ("Lewis"). Tr. 24. Lewis is an employee of the Mississippi Bureau of Narcotics ("MBN"). Tr. 25. Lewis received a complaint against the Respondent on January 18, 2015. Tr. 25. Lewis spoke with CI and her husband, who had made the complaint together. Tr. 25, 29–31. Other than this conversation, Lewis had no further contact with CI. Tr. 28. Based on the nature of the complaint, Lewis contacted MBN's diversion unit, which began investigating the Respondent. Tr. 26–27, 31. During 2015, Lewis participated in the investigation by assisting with surveillance on March 27, April 8, April 29, and October 16. Tr. 27. Lewis's testimony was thorough, detailed, and internally consistent. Therefore, I merit it as credible in this Recommended Decision.

Second, the Government called Mary Flinchum ("Flinchum"). Tr. 33. Flinchum is a lieutenant for the MBN and a task force officer for the DEA's Tactical Diversion Squad. Tr. 33–34. Flinchum received an intelligence report about the Respondent from MBN. Tr. 35. Flinchum interviewed CI and her husband, separately and together, about their complaint to MBN. Tr. 36, 82. Flinchum helped decide that MBN should investigate the Respondent. Tr. 36–37. Flinchum also communicated with the Mississippi State Board of Medical Licensure ("Mississippi Board"), which was conducting an independent investigation concerning the Respondent. Tr. 58–59. Flinchum was familiar with an undercover investigation of the Respondent during March, April, and October of 2015. Tr. 77–81. Later, Flinchum was recalled to offer further testimony concerning the October 2015 undercover operation. Tr. 449–50. Through Flinchum's testimony, the Government authenticated and successfully offered into evidence Government Exhibits ("GE-") 13 through 21, 27 through 29, 38 through 40, and 53. Tr. 38–57. I find all of these exhibits to be accurate, authentic, and meriting credibility. On cross-examination, the Respondent authenticated and successfully offered into evidence GE–2. Tr. 62–63. I find that Flinchum's testimony was thorough, detailed, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Third, the Government called Undercover Agent #1[5] ("Agent 1"). Tr. 89. Agent 1 is a female DEA task force officer and former MBN Agent. Tr. 89–90. Agent 1 participated in an undercover investigation of the Respondent. Tr. 90–91. Agent 1 attended undercover medical appointments with the Respondent on four occasions in 2015: March 27, April 8, April 29, and October 16. Tr. 91, 102, 111, 119. Agent 1 also accompanied CI to a rendezvous with the Respondent at a Walmart before the second undercover appointment on April 8, 2015. Tr. 128–29. Through Agent 1's testimony, the Government authenticated and successfully offered into evidence GE–9 through 12, 24 through 26, 30 through 33, 42 through 47, and 54. Tr. 91–128. I find all of these exhibits to be accurate, authentic, and meriting credibility. I also find that Agent 1's testimony was thorough, detailed, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Fourth, the Government called Undercover Agent #2 ("Agent 2"). Tr. 141. Agent 2 is a female MBN agent. Tr. 141. Agent 2 participated in the undercover investigation of the Respondent. Tr. 142. Agent 2 attended an undercover medical appointment with the Respondent on April 29, 2015. Tr. 143. Through Agent 2's testimony, the Government authenticated and successfully offered into evidence GE–34 through 37. Tr. 143–51. I find these exhibits to be accurate, authentic, and meriting full credibility. I also find that Agent 2's testimony was thorough, detailed, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

Fifth, the Government called MBN Agent Charles Causey ("Causey"). Tr. 159. In 2015, Causey assisted with audiovisual surveillance for the DEA and MBN's undercover investigation of the Respondent on March 27, April 8, April 29, and October 16. Tr. 162–63. Causey testified that the video recordings of these undercover operations may contain incorrect internal date/time stamps, and that the dates and times on the video recordings do not necessarily correspond to the actual dates and times on which the video recordings were made. Tr. 165–66. I find that Causey's testimony was thorough, detailed, and internally consistent. Therefore, I merit his testimony as credible in this Recommended Decision.

Sixth, the Government called Leslie Ross ("Ross"). Tr. 168. Ross is an investigations supervisor for the Mississippi Board and a task force officer for the DEA's Tactical Diversion Squad. Tr. 168–69. The Mississippi Board reviews and issues medical licenses, promulgates rules and regulations for the practice of medicine in Mississippi, investigates complaints about Mississippi licensees, and imposes disciplinary action when necessary. Tr. 170. Several days before the Mississippi Board closed its investigation concerning the Respondent, Ross received a call from Agent Flinchum, advising Ross that the DEA and the MBN were investigating the Respondent. Tr. 194–95, 210. Ross explained that the phone call influenced the Mississippi Board's decision to close its case because it was the Mississippi Board's custom "to back off and let a criminal agency pursue their case." Tr. 210. Without interviewing CI, the Mississippi Board closed its investigation. Tr. 196. Ross also helped author part of Mississippi Administrative Rule 1.5, which regulates diet medication prescriptions in Mississippi. Tr. 172. Ross established the foundation for the Court to take official notice of Mississippi Administrative Rules 1.1, 1.2, 1.4, 1.10, and 1.16. Tr. 188–93. Additionally, while Ross did not conduct the Mississippi Board's investigation of the Respondent, she supervised Todd Pohnert, who conducted the investigation. Tr. 170, 173. Ross served administrative subpoenas for information about the Respondent to two Mississippi pharmacies, one in McComb and one in Brookhaven. Tr. 185. I find that Ross' testimony was thorough, detailed, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision. Through Ross' testimony, the Government authenticated and successfully offered into evidence GE–3 and 8. Tr. 171–78. I find these exhibits to be accurate, authentic, and meriting credibility. Furthermore, through Ross' testimony, the Government established some foundation for GE–7 and 55. Tr. 185–88.

Seventh, the Government called CI. Tr. 212. CI testified about her relationship with the Respondent and how and why she obtained controlled substance prescriptions from him. Tr. 212–31.[6] Through CI's testimony, the Respondent admitted GE–49, 56, and 57. Tr. 284, 300–03, 335–38. I find these exhibits to be generally accurate, authentic, and meriting credibility. I also find that CI's testimony was generally forthright, internally consistent, and generally merited credibility[7] in this Recommended Decision.

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[4] Although the Government also called Antoine Battle to the stand, the Government did not elicit any testimony from Mr. Battle, and he was excused without testifying. Tr. 155–58.

[5] Pursuant to the Prehearing Ruling and Protective Order, the identities of the undercover agents are not disclosed in this Recommended Decision. ALJ–9.

Eighth, the Government called James Pacheco (''Pacheco''). Tr. 385. Pacheco is an agent for the MBN and a task force officer for the DEA's Tactical Diversion Squad. Tr. 386. Pacheco participated in the undercover investigation of the Respondent by coordinating the surveillance aspect of the investigation. Tr. 388. Pacheco assisted with physical surveillance of the Respondent and CI during an undercover operation at a Walmart on April 8, 2015. Tr. 388–89. Pacheco personally observed most of the operation at Walmart. Tr. 389. Pacheco also testified that he listened to the undercover operation conducted at the Respondent's clinic in October 2015. Tr. 406–07. Through Pacheco's testimony, the Government authenticated and successfully offered into evidence GE–22 and 23. Tr. 387–93. I find these exhibits to be accurate, authentic, and meriting credibility. I also find that Pacheco's testimony was thorough, detailed, and internally consistent. Therefore, I merit his testimony as credible in this Recommended Decision.

The Government's ninth witness was Maria Gilbert (''Gilbert''). Tr. 409. Gilbert is a DEA diversion investigator, and was a case agent in the investigation of the Respondent. Tr. 409–10. Gilbert helped submit the evidence acquired by the undercover agents into a DEA evidence locker. Tr. 440. Gilbert also directed DEA personnel to obtain Prescription Monitoring Program (''PMP'') reports during the investigation. Tr. 438. Gilbert created the administrative subpoenas issued to pharmacies to obtain information about the Respondent. Tr. 412. Gilbert helped conduct an administrative search of the Respondent's office. Tr. 427–28. Through Gilbert's testimony, the Government authenticated and successfully offered into evidence GE–7, 41, 48, 50 through 52, 55, and 58 through 60. Tr. 411–18, 427–39. I find these exhibits to be accurate, uncontested, and meriting credibility. I also find that Gilbert's testimony was thorough, detailed, and internally consistent. Therefore, I merit her testimony as credible in this Recommended Decision.

The Respondent did not call any witnesses or offer any of his proposed exhibits into evidence. Tr. 458.

The factual findings below are based on a preponderance of the evidence, including the detailed, credible, and competent testimony of the aforementioned witnesses, the exhibits entered into evidence, and the record before me.

FACTUAL FINDINGS

1. The Respondent has not previously been convicted of any crime related to controlled substances. GE–1, at 1. The Respondent has never had his state medical license revoked, suspended, denied, restricted, or placed on probation. GE–1, at 1.

The Respondent's Relationship with CI

2. The Respondent and CI became Facebook friends and began talking with each other in January 2014. Tr. 213, 237. CI asked the Respondent questions about the health of Kid 1.[8] Tr. 213–14, 246–47, 261–62. The Respondent performed a tonsillectomy on Kid 1 and placed tubes in his ears on January 30, 2014. GE–57, at 13, 19–20; Tr. 219, 235, 285. Following Kid 1's tonsillectomy, CI asked the Respondent for medication for Kid 1's medical condition; the Respondent was willing to write prescriptions for Kid 1. GE–57, at 5–6; Tr. 246–47, 249. Around that time, CI and the Respondent became friends and began texting and talking on the phone. Tr. 213–14, 240.

3. In the spring of 2014, CI and the Respondent began to have a consensual sexual relationship. Tr. 213, 218–19, 290–92, 296, 359. During the summer of 2014, CI and the Respondent saw each other very often. Tr. 324. CI and the Respondent communicated frequently by texting and calling each other on their cell phones. Tr. 355–56.

4. CI engaged in a sexual affair with the Respondent because she was infatuated with him and because she wanted to obtain controlled substances for her recreational use. Tr. 291–92. The controlled substances, however, were not a prerequisite for sexual relations. Tr. 289.

5. The sexual relationship between CI and the Respondent ended in November 2014. Tr. 219.

A. The Respondent's Medical Treatment of CI and Her Children

6. The Respondent provided medical treatment to CI several times, beginning in 2010. GE–2, at 12–13; Tr. 215, 277. Specifically, the Respondent treated CI for a sinus infection, vertigo, and migraines. GE–2, at 12–13; Tr. 215, 277–78, 287, 321. CI had a serious migraine condition that caused her to seek treatment in emergency rooms on four occasions. Tr. 278–80, 347. CI discussed her migraines and hospitalizations with the Respondent, who gave her information about migraines. Tr. 282, 287. The Respondent prescribed Maxalt[9] to CI to treat her migraines. GE–2, at 12; Tr. 215–16, 283.

7. The Respondent had a patient file for CI and wrote notes therein about her treatment. *See* GE–2, at 12–13. The Respondent conducted two physical examinations of CI, once when he was treating her for a sinus infection, and again when he was treating her for a migraine headache.[10] GE–2, at 12–13; Tr. 322. The Respondent also requested a CT[11] sinus scan for CI in 2014. GE–2, at 12, 14. A CT scan showed that CI's sinuses were ''clear [and] scant thickening in LNF duct.'' GE–2, at 14.

8. CI took Kid 1 and Kid 2 to appointments with the Respondent. Tr. 219, 261–62, 285–86, 335–36, 338; *see, e.g.,* GE–56, at 3–4; GE–57, at 6, 9–10. The Respondent conducted legitimate medical procedures on both children and saw the children for follow-up appointments. GE–56, at 3–4; GE–57, at 5–6; Tr. 219, 261–62.

9. CI sent the Respondent at least one message via social media requesting his medical advice about Kid 1's condition. Tr. 262–63. CI communicated with the Respondent about the physical

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[6] The Respondent asked CI extensively about an exhibit, pre-marked for identification as Respondent's Exhibit (''RE-'') 1. *See generally* Tr. 231–73. However, the Respondent never offered RE–1 into evidence. Therefore, the contents of RE–1 are not considered in this Recommended Decision.

[7] There were some inconsistencies in CI's lengthy testimony. First, when asked if she paid cash for prescriptions from the Respondent, CI answered that she believed she always used insurance. Tr. 360. However, CI's Prescription Monitoring Program report shows that, in 2014, CI paid for prescriptions from the Respondent with cash 15 times, and used her insurance only 5 times. *See* GE–49, at 1–3. Second, CI suggested that it was the Respondent's idea for CI to send a friend into his office to get prescriptions for her. Tr. 345–47. However, audio recordings of the Respondent's telephone calls with CI suggest that it was CI's idea for her to send a friend into the Respondent's office to get prescriptions for CI. *See* GE–16, file 2015–03–16_18–51–48_EDT, at 20–21; GE–16, file 2015–03–18_11–03–33_EDT, at 2. Third, CI testified that the Respondent only conducted a physical examination of her one time. Tr. 322. The Respondent's patient file for CI seems to indicate, however, that the Respondent gave CI some sort of examination on both April 21 and September 2 of 2014. GE–2, at 12. In these three instances, I do not find CI's testimony credible.

[8] *See* Stipulation (''Stip.'') 4; *see also* ALJ–9, at 5.

[9] Maxalt, or rizatriptan benzoate, is not a federally controlled substance. *See generally* 21 CFR §§ 1308.11–1308.15 (2015).

[10] *See supra* note 7.

[11] Computerized tomography.

condition of her children to get his medical advice. Tr. 263–65.

10. Near a date stamp reading "February 4, 2014," the Respondent recorded in Kid 1's medical file that CI had migraines, that she may call in for a prescription if needed, and that he discussed phentermine [12] with her. GE–57, at 6; *see* Tr. 286. The Respondent's patient file for CI also contains a telephone request form, dated July 18, 2014, and signed by the Respondent, which states that CI requested a phentermine refill. GE–2, at 15. CI's patient file, however, does not note any reasons that the Respondent prescribed phentermine to CI. *See* GE–2, at 12–13.

B. CI's Drug Use

11. Prior to her relationship with the Respondent, CI took controlled substances, including hydrocodone, which were prescribed by numerous other doctors to help treat pain resulting from four lithotripsies, kidney stones, a broken tailbone, a root canal, and TMJ [13]. GE–49, at 2; Tr. 214, 275–76, 304–09. CI told the Respondent about these prescriptions. Tr. 309.

12. CI occasionally used Adderall for nonmedicinal purposes. Tr. 215. CI had not used cough syrup for nonmedicinal purposes prior to her relationship with the Respondent. Tr. 215.

13. After Kid 1 had his tonsils removed on January 30, 2014, CI took some of Kid 1's pain medication. Tr. 273–74, 276. As a result of the tonsillectomy, the Respondent prescribed two different forms of hydrocodone for Kid 1. GE–51, at 1; GE–57, at 6, 14, 22.

14. The Respondent first prescribed cough syrup for Kid 2 on January 24, 2014. GE–50, at 1; GE–56, at 4. The Respondent again prescribed cough syrup for Kid 2 in February 2014. Tr. 216, 258–59; GE–50, at 1; GE–56, at 4. The Respondent did not examine Kid 2 before he prescribed cough syrup for her. Tr. 217, 251; *see* GE–56, at 4.

15. CI talked with the Respondent about prescribing a "big bottle" of cough syrup so that CI could drink it. Tr. 216, 251–52, 268, 273. CI thought that the Respondent knew she did not have a cough. Tr. 216, 251–52, 268. In February 2014, CI asked the Respondent to prescribe [14] a "big bottle" of hydrocodone cough syrup for Kid 2. Tr. 216–17, 250, 252–53, 259. At that time, CI told the Respondent that Kid 2 had a cough. Tr. 250–51, 253–55. On February 7, 2014, the Respondent doubled the size of Kid 2's prescription for cough syrup. GE–50, at 1; GE–55, at 1–2.

16. CI told the Respondent when Kid 1 or Kid 2 had a cough. Tr. 250. CI, however, did not bring her children to see the Respondent regarding a cough; she requested cough syrup from the Respondent because she liked drinking it. Tr. 220, 273; *see generally* GE–56, at 3–4; GE–57, at 5–6.

17. The Respondent prescribed Norco, Xanax, and Adipex to CI on multiple occasions. Tr. 26; GE–49. The Respondent prescribed Norco [15] to CI, which she took daily instead of as needed. Tr. 297. CI took hydrocodone "[j]ust for fun." Tr. 298. CI would tell the Respondent when she ran low on a prescription, and he would give her another prescription.[16] Tr. 298–99. He advised her that hydrocodone could cause migraines. Tr. 298–99.

18. On several occasions, the Respondent provided prescriptions to CI while he was at CI's house. Tr. 217–18; *see* Tr. 26. On those occasions, the Respondent did not communicate a diagnosis to CI or perform a physical examination of CI. Tr. 218. Sometimes, CI took her children to appointments with the Respondent as an excuse to see the Respondent, who would then occasionally give prescriptions to CI. Tr. 219–20. On one occasion, the Respondent met CI in the garden section of a Walmart, where he gave her prescriptions for cough syrup and pain medication. Tr. 218.

19. At times, CI told the Respondent about her children's pain or physical conditions to get prescriptions for her own personal use. Tr. 267. CI would occasionally administer the prescribed medication to her children. Tr. 270–72.

20. CI requested that the Respondent write a prescription for Adderall for her, but he declined to do so. Tr. 223. In the spring of 2014, CI asked the Respondent to write her a prescription for Adipex, a weight loss drug. Tr. 223–24, 288–89. The Respondent wrote prescriptions and refills for Adipex to CI. GE–49, at 1–2; Tr. 223–24. CI used Adipex for approximately three months. Tr. 224. The Respondent did not conduct a physical examination of CI focused on weight issues at any point before or while CI took Adipex, and the Respondent did not discuss alternative weight loss treatments with CI. Tr. 224–25; *see* GE–2, at 12–13.

21. CI had anxiety, which she discussed with the Respondent. Tr. 322. The Respondent told her to visit a certain psychiatrist. Tr. 225, 295. CI visited that psychiatrist twice. Tr. 225. The psychiatrist prescribed a low dosage of time-release Xanax [17]. Tr. 225, 295, 304; *see* GE–49, at 1. The Respondent then prescribed [18] a stronger dosage of Xanax to CI. Tr. 226; *see* GE–49, at 1.

22. The Respondent wrote nine prescriptions [19] to CI, contained in GE–7 and 41, which are not documented in the Respondent's patient file for CI. *Compare* GE–2, at 12–13 (containing the Respondent's patient file for CI), *with* GE–7, at 1–2 (containing a prescription written by the Respondent to CI), *and* GE–41 (containing prescriptions written by the Respondent and filled by CI), *and* GE–49 (containing CI's PMP report); *see* Tr. 364–77. The Respondent's patient file for CI does not include any notes from any examinations on the dates on which the Respondent wrote these nine prescriptions. GE–2, at 12–13. CI did not have a physical examination or receive counseling before the Respondent gave her any of these prescriptions. Tr. 384; *see* GE–2, at 12–13.[20]

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[12] CI denied asking the Respondent for phentermine in February 2014. Tr. 286–88. Phentermine is another name for Adipex. *See* Stip. 8; Tr. 288.

[13] Temporomandibular joint dysfunction, or lockjaw.

[14] CI later testified that this was a refill of a prescription written by the Respondent. Tr. 272–73.

[15] Norco is a hydrocodone combination product. *See* Stip. 5.

[16] Specifically, CI testified that when she ran low on a prescription, the Respondent would refill it. Tr. 298–99. Refills are not authorized for hydrocodone combination products, such as Norco. *Compare* 21 U.S.C. § 829(a), *with* Stip. 6. The record does not contain any evidence that the Respondent attempted to give CI a refill on a hydrocodone combination product. Therefore, I interpret CI's statement as meaning that whenever she ran low on a prescription, she would tell the Respondent, and he would issue another prescription to her.

[17] Xanax is a brand name for alprazolam, which is a benzodiazepine and a Schedule IV controlled substance. Stip. 7; *see* 21 CFR § 1308.14(c)(2); Tr. 304.

[18] CI testified that this prescription was a refill prescription, but that it was for a different dosage. Tr. 295–96.

[19] Seven of these prescriptions, written to CI in 2014, were as follows: May 19 for Adipex; May 22 for Norco; June 17 for Norco; July 24 for Adipex; September 8 for Adipex; September 11 for Norco; and October 6 for Xanax. *Compare* GE–2, at 12–13, *with* GE–41, at 1–7, 12–13, and 18–23, *and* GE–49. The Respondent wrote another prescription for Adipex to CI on April 9, 2014. *Compare* GE–2, at 12–13, *with* GE–7, at 1–2, *and* GE–49. The Respondent also wrote a prescription for Hycodan to CI, dated December 3, 2014, but CI's PMP report said that the prescription was written on December 4, 2014. *Compare* GE–41, at 28–29, *with* GE–49. Regardless of when this prescription was actually written, it was not documented in CI's patient file. *See* GE–2, at 12–13.

[20] CI testified about a prescription that is not in GE–41. Tr. 364, 369–70. The prescription allegedly was written in her name by the Respondent. Tr. 369–70. The prescription allegedly was dated October 29, 2014. Tr. 369–70. The Respondent's PMP report likewise lists a prescription for hydrocodone-acetaminophen (Norco) prescribed by the Respondent on October 29, 2014. GE–49, at 1. However, neither of the two copies of GE–41 submitted to me includes this prescription. Examination of both submitted copies of GE–41

Continued

23. Two prescriptions written by the Respondent to Kid 1 are not documented in Kid 1's medical chart. *Compare* GE–51 (containing Kid 1's PMP report and listing prescriptions from June 17 and November 19 of 2014), *and* GE–55, at 3–4, 11–12 (containing prescriptions from June 17 and November 19 of 2014), *with* GE–57 (containing Kid 1's medical file, which does not include any examination or prescription notes for June 17 or November 19 of 2014); *see also* Tr. 377–81. Likewise, a prescription written by the Respondent to Kid 2 is not documented in Kid 2's medical chart. *Compare* GE–50 (containing Kid 2's PMP report and listing a prescription written on July 23, 2014), *and* GE–55, at 5–6 (containing a prescription dated July 23, 2014), *with* GE–56 (containing Kid 2's medical file, which does not include any examination notes or prescription notes for July 23, 2013).

24. On one occasion in early fall of 2014, following CI's complaint of a severe migraine, the Respondent prescribed Demerol to CI. Tr. 222, 296–97, 317–18, 382. Next to the date "September 2, 2014" in CI's medical chart, the Respondent wrote that he refilled her prescription of phentermine, looked at her ears and nose, and counselled her. GE–2, at 12; Tr. 323. He also wrote that he prescribed Demerol and Xanax to CI. GE–2, at 12. CI did not ask the Respondent for Demerol. Tr. 296, 318.

25. CI's husband discovered that CI was having an affair with the Respondent. Tr. 26, 320. Sometime after the discovery, in December 2014, CI attempted suicide using the Demerol the Respondent prescribed to her. Tr. 222, 314–17. CI went to a mental institution for a week following her suicide attempt. Tr. 227, 309. In January 2015, CI told the Respondent that she had tried to kill herself. Tr. 226–27, 309–11.

C. The MBN Complaint

26. After CI's husband discovered the affair and CI attempted to commit suicide, CI and her husband made a complaint against the Respondent to the MBN. Tr. 25, 29–31, 71, 228–29, 339–40. CI told MBN investigators that she got medications from the Respondent for nonmedicinal purposes because she enjoyed using them. Tr. 84.

D. The Anonymous Letter

27. The Mississippi Board received an unsigned letter, allegedly from CI's husband, which complained about the extramarital affair between CI and the Respondent. GE–3, at 3; Tr. 58, 66. The Mississippi Board and MBN both received a copy of the letter. Tr. 66–67, 70–71, 398–99. Several witnesses testified that CI's husband was not the author of this letter. Tr. 67–70, 326, 394, 396. The author of the letter is unknown. Tr. 67–70, 201, 326, 394–95.

28. The letter was written in the first person, and CI's husband's name was typewritten on the bottom of the letter, along with CI's date of birth and social security number. GE–3, at 3. The letter said that the author's wife, CI, had an affair with the Respondent for over a year, and that the author did not know about it until he found a box of empty pill bottles that the Respondent had prescribed to CI, even though CI was not his patient. GE–3, at 3. The letter was stamped as received by the Mississippi Board on February 19, 2015. GE–3, at 3.

29. By the time the MBN received a copy of the letter, it had already begun its investigation of the Respondent because of the complaint made by CI and her husband. Tr. 71, 74–76. After receiving a copy of the letter, the Mississippi Board began conducting an independent investigation of the Respondent. Tr. 58, 61, 203.

E. The Mississippi Board Investigation

30. A Mississippi Board investigator met with the Respondent regarding the anonymous letter. GE–3, at 4–6. At that time, the Mississippi Board was unaware that the DEA was conducting a simultaneous investigation of the Respondent. Tr. 180.

31. In response to the investigator's inquiry, the Respondent said that he only saw CI when she or her children had appointments, and had not seen CI outside of his office. GE–3, at 5; Tr. 179, 202. The Respondent suggested that he had not engaged in sexual misconduct with CI. GE–3, at 5; Tr. 180, 207. The Respondent also suggested that he was not aware that CI had attempted to commit suicide or had been committed to a mental hospital. GE–3, at 5, 7.

32. The investigator made copies of CI's patient charts and found several shortcomings with CI's medical records. GE–3, at 4–5; Tr. 180, 197. First, the investigator found seven prescriptions in CI's PMP report that were not documented in the Respondent's patient file for CI. GE–3, at 5. The Respondent explained that he might have documented the missing prescriptions in his patient files for CI's children instead. GE–3, at 5.

33. Second, the investigator found that CI's patient file did not include any notes about CI's vitals, height/weight, BMI, or alternative weight control treatment plans, and did not indicate that CI received any counseling about other weight loss options. GE–3, at 5; Tr. 180.

34. Following the investigator's visit, the Mississippi Board sent the Respondent a copy of the anonymous letter purportedly from CI's husband.[21] *See* GE–2, at 6–8. The investigator told the Respondent that he should send a letter to the Mississippi Board as a follow-up from the investigator's visit. GE–3, at 5; Tr. 179.

35. The Respondent sent a letter to the Mississippi Board. GE–3, at 7–8; Tr. 179–80. Therein, the Respondent denied knowing that CI had overdosed.[22] GE–3, at 7; Tr. 180. The Respondent stated that he was "appalled, outraged, and disgusted" by the anonymous letter's allegations. GE–3, at 7; Tr. 208. The Respondent wrote that the medications CI used to overdose "were legitimately prescribed for valid medical problems." GE–3, at 7. The Respondent wrote that he was unaware that CI had received controlled substances from other prescribers and that CI did not show "any hint of drug-seeking behavior." GE–3, at 7. The Respondent acknowledged that he should not refill medications for a parent during a child's visit without pulling the parent's chart, and said that he would not do so in the future. GE–3, at 7. The Respondent stated that he would not refill diet drugs for patients in the future without completing the appropriate documentation. GE–3, at 7.

36. The Mississippi Board contemplated closing its investigation of the Respondent because it did not have enough evidence supporting the allegations of the Respondent's sexual misconduct. Tr. 181, 184, 194–95, 197, 209–10. Throughout the course of its investigation, however, the Mississippi Board never interviewed CI. Tr. 196.

37. On March 20, 2015, while the Mississippi Board was contemplating closing its investigation, Flinchum

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reveals that no pages of GE–41 are missing. At the hearing, however, Government counsel provided CI with an excerpt of what he said was "part of Exhibit 41," and he provided the Respondent and the ALJ with a copy of what was handed to the witness. Tr. 364. That excerpt has now been included in the administrative record as ALJ–29. Comparing ALJ–29 with GE–41, I have determined that the witness did, in fact, examine a prescription dated October 29, 2014. That prescription, however, was never offered into evidence. Furthermore, the witness was never asked if the prescription, dated October 29, 2014, refreshed her memory of having received the prescription. Accordingly, I decline to find that the Government presented sufficient evidence to establish that the Respondent wrote a prescription to CI on October 29, 2014. Following the hearing, the parties were provided with copies of ALJ–29.

[21] The handwritten notation on the bottom of the letter was likely added by a Mississippi Board investigator. Tr. 87; *see* GE–2, at 6.

[22] Specifically, the Respondent wrote that he was "sorry to learn that [CI] may have deliberately taken an overdose." GE–3, at 7.

contacted the Mississippi Board and requested, on the DEA's behalf, that the Mississippi Board discontinue its investigation of, and communication with, the Respondent. GE–3, at 2; Tr. 60–61, 181, 209. The Mississippi Board customarily will discontinue an investigation to allow a criminal agency to pursue a case. Tr. 210.

38. The Mississippi Board closed its investigation of the Respondent on March 23, 2015. GE–3, at 1; Tr. 181. A letter from the Mississippi Board to the Respondent terminated the Board's investigation. GE–3 at 1; Tr. 183. The letter stated that the Mississippi Board concluded its investigation and that, after a thorough review of the information and facts from the investigation, it decided not to recommend any formal action. GE–3, at 1. This letter was a truthful and accurate reflection of the Board's reasons for terminating the investigation. Tr. 64–65, 86, 195–97.

39. The letter also cautioned the Respondent against "authorizing refills for Phentermine/Adipex without benefit of a medical examination." GE–3, at 1 (discussing Mississippi Administrative Rule 1.5(E)).

40. The letter told the Respondent that the Mississippi Board had found some deficiencies with his medical records. Tr. 181, 183–84, 203. The letter did not exonerate the Respondent, but warned him about his inadequate documentation of weight loss prescriptions. Tr. 184, 203.

F. DEA Undercover Operations

41. The DEA began undercover operations concerning the Respondent in March 2015. Tr. 77–78.

42. CI was told that if she cooperated with law enforcement, she would not be in any trouble. Tr. 342–43. CI signed a confidential informant agreement with the DEA. Tr. 343–44, 394.

43. The DEA instructed CI not to have any contact [23] with the Respondent unless the DEA supervised the contact. Tr. 350. CI did not comply with this instruction and met the Respondent one time without DEA's supervision. Tr. 353, 358.

44. With CI's consent, the DEA gave CI a telephone number that recorded all calls and text messages exchanged between CI and the Respondent. Tr. 37–38, 84–85, 230. This telephone number operated through an application that the DEA installed on CI's cellular phone. Tr. 382. This application automatically recorded all calls, conversations, and multimedia messages exchanged between CI and the Respondent. Tr. 37–38, 85–86.

45. CI called and texted the Respondent outside of the presence of MBN and DEA agents. Tr. 85–86. The DEA did not tell CI what to say to the Respondent. Tr. 85–86.

i. Interactions Between the Respondent and CI Before the First Undercover Appointment

46. The DEA agents asked CI to contact the Respondent by phone or by text message and ask him for Norco and cough syrup. Tr. 346, 348–49.

47. On March 16, 2015, at approximately 6:51 p.m., the Respondent and CI spoke on the phone. GE–15–16. CI asked the Respondent to meet her at Walmart and give her a prescription for something. GE–16, file 2015–03–16_18–51–48_EDT, at 19; *see* Tr. 345. The Respondent said he could not do that because the Mississippi Board was watching him and he could go to jail or lose his license. GE–16, file 2015–03–16_18–51–48_EDT, at 19–20; *see* Tr. 230, 345–47. He said that everything he had prescribed to CI was legitimate and written in her chart. GE–16, file 2015–03–16_18–51–48_EDT, at 20. After CI again asked the Respondent several times to give her a prescription, CI asked him instead to write a prescription for someone else.[24] *Id.* The Respondent said he could prescribe to anyone who came into his office, and what they did with their prescriptions was "their business," but that it had "to be a legitimate thing." *Id.* at 21. CI asked him multiple times to write prescriptions for her, but in different names, and the Respondent said he could not do so without someone coming for a visit and having a chart. *Id.* The Respondent said he could "probably pilfer" some medication from his wife for CI. *Id.* at 22. CI repeatedly asked the Respondent to get her some controlled substances, and the Respondent repeatedly said he would see what he could do. *Id.* at 24–26.

48. On March 17, 2015, at approximately 1:07 p.m., the Respondent and CI spoke on the phone. GE–15–16. CI asked the Respondent to slip "a couple Lorcets" into her mailbox. GE–16, file 2015–03–17_13–07–36_EDT, at 4. The Respondent joked, "I need to learn to play the guitar so you could be getting sex, drugs and rock and roll, you know." *Id.* CI asked the Respondent to "sneak [her] some meds." *Id.* at 7. The Respondent said, "I've got your request and I'm telling you that is highly, highly dangerous for me." *Id.*

49. On March 18, 2015, at approximately 11:03 a.m., the Respondent and CI spoke on the phone. GE–15–16. CI suggested that the Respondent could write a prescription in Kid 1's name. GE–16, file 2015–03–18_11–03–33_EDT, at 1. The Respondent responded sarcastically and attempted to change the subject. *Id.* at 1–2. CI said that she really needed him to find a way to write her a prescription. *Id.* at 2. The Respondent said he did not know how to do that. *Id.* CI suggested that he could write a prescription in someone else's name. *Id.* The Respondent said he would "have to have somebody that's legitimate" and "what they did with the medicine[,] that was up to them . . . somebody that's trustworthy." *Id.* at 3. The Respondent indicated that it was like a "federal crime when you write medicine to—that are diverted to somebody else." *Id.* CI said that the Respondent used to write her prescriptions "all the time." *Id.* The Respondent said, "Yeah, but I wrote it for you." *Id.* CI recalled that the Respondent "used to bring [his] prescription pad over and a bottle of vodka," and that she "miss[ed] those days." *Id.* The Respondent replied, "I know, me too." *Id.* The Respondent joked with CI that it was good to have a boyfriend with a prescription pad. *Id.* at 4.

50. On March 25, 2015, at approximately 10:36 a.m., the Respondent and CI spoke on the phone. GE–17, at 1–5.[25] CI asked the Respondent if he would write a prescription to another person. GE–17, at 2. The Respondent remarked that it was dangerous and it would have to be to an established patient; he suggested that she get another doctor to write a prescription for her. GE–17, at 2. CI insisted, and the Respondent said "it has to be legitimate" and for a "legitimate patient" because the Mississippi Board was watching him. GE–17, at 2. The Respondent said he could treat a patient for CI if the patient had headaches and anxiety. GE–17, at 3. The Respondent said, "what he does with 'em is his business." GE–17, at 3. CI asked the Respondent if he would write something to her friend who came in with a headache; the Respondent said, "Yeah, I could write him something." GE–17, at 3. CI clarified that the prescription would really be for her, and requested that he prescribe "Lorcet or something;" the Respondent said, "Yeah, I could write him some—

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[23] The DEA did not ask CI to attend an undercover appointment with the Respondent because CI had a physical relationship with the Respondent, and because CI said that she was addicted to cough syrup. Tr. 400.

[24] *Contra* Tr. 346; *see supra* note 7.

[25] *See* GE–16, file 2015–03–25_10–36–40_EDT.

yeah, some stuff like that.'' GE–17, at 3. The Respondent cautioned CI that taking too many Lorcet or Demerol would be harmful and painful to her. GE–17, at 4. CI said she just wanted ''some pain pills from [her] boyfriend.'' GE–17, at 4.

51. On March 25, 2015, at approximately 11:43 a.m., the Respondent texted CI, ''I won't be in the office tomorrow. I could see her Friday.'' GE–53, file 2015–03–25_11–43–42_EDT. CI texted back, ''Ok:) she is a real cool girl. I use [sic] to party with her.'' GE–53, file 2015–03–25_11–47–23_EDT; *see* Tr. 349.

52. On March 25, 2015, at approximately 2:36 p.m., the Respondent and CI spoke on the phone. GE–17, at 6–8.[26] The Respondent asked CI for her friend's name. GE–17, at 6–8. CI told the Respondent the alias first name of Agent 1. GE–17, at 6–7. The Respondent said, ''If she's coming in for what I think she's coming in, tell her not to tell me that. That needs to be your secret. I don't wanna know that. She needs to have a headache and I will treat her for a headache, and so [I] don't mind giving her prescriptions to treat a headache.'' GE–17, at 7. The Respondent discussed the medications he could prescribe to Agent 1 and told CI that they ''would be perfectly appropriate for you to take.'' GE–17, at 7; *see* Tr. 349 (noting that the Respondent knew that Agent 1 was not a real patient and that medication prescribed to Agent 1 would be given to CI).

53. On March 26, 2015, at approximately 11:18 a.m., the Respondent and CI spoke on the phone. GE–18.[27] CI told the Respondent that Agent 1 had an appointment with him ''tomorrow at 2:00—2:10, I think.'' GE–18, at 3. The Respondent replied, ''Okay. We'll see if we can't get my girlfriend fixed up.'' GE–18, at 3. The Respondent said CI should remind Agent 1 to ''play it straight'' and tell the Respondent what he to needed to write on a chart to ''keep the medical examiners at bay . . . .'' GE–18, at 3. CI asked him if he would prescribe Norco to Agent 1. GE–18, at 3. The Respondent said, ''Yeah, I'll write her Norco and some more Maxalt, and then you can have some Maxalt also. Just remember to hide it.'' GE–18, at 3.

54. Based on Findings of Fact 47 through 53 and the transcript at pages 91, 230, and 349, I find that, by the time the Respondent met with Agent 1 on March 27, 2015, the Respondent knew that Agent 1 was not a legitimate patient and that any medication he prescribed to her at that appointment would be given to and used by CI.

ii. Undercover Appointment #1: March 27, 2015

55. Agent 1's first appointment with the Respondent was on March 27, 2015. GE–10; Tr. 91. Upon arriving at the Respondent's clinic, Agent 1 signed in, completed paperwork, and waited in the Respondent's waiting room. GE–9; Tr. 92. The Respondent's nurse called Agent 1 back into an examination room and spoke briefly with her. GE–9; Tr. 92, 94.

56. Agent 1 met with the Respondent. GE–9–10; Tr. 91; *see* GE–59 (containing the Respondent's patient file for Agent 1). The appointment lasted approximately seven minutes. GE–9. When the Respondent asked Agent 1 what her problem was, she told him, ''Just kind of a whole head thang [sic].'' GE–10, at 1; Tr. 94. The Respondent asked Agent 1 how long her head had been bothering her, and she indicated just a few days. GE–9–10. The Respondent quickly looked into Agent 1's ears, nose, and throat. GE–9–10; Tr. 94, 132. The Respondent asked her if she was dizzy, nauseous, or taking other medication. GE–9–10. He advised her that Maxalt works well for sinus headaches and gave her instructions for taking her prescriptions. GE–9–10. The Respondent did not communicate any diagnosis to Agent 1, nor did he record a diagnosis in her patient file.[28] GE–9–10; GE–59, at 4.

57. Agent 1 asked the Respondent if he could help her with her weight loss. GE–9–10. The Respondent declined to prescribe anything for weight loss to Agent 1; he said that it was not his area of expertise and it was heavily regulated by the Mississippi Board. GE–10, at 2. He recommended that she could go to a licensed diet center for assistance. GE–10, at 3.

58. The Respondent wrote two prescriptions for Agent 1: one non-refillable prescription for Norco, and one refillable prescription for Maxalt. GE–11–12; Tr. 95. The Respondent told Agent 1 that he would give her ''lots of refills'' on the Maxalt. GE–10, at 1.

59. That same day, CI and the Respondent had a phone conversation about the Respondent's meeting with CI's ''friend,'' Agent 1. GE–13–14; GE–20, file Post Buy CI Call With STEWART 3–27–2015. The Respondent said he enjoyed meeting Agent 1 and that he was ''hopeful that that helps'' CI. GE–14, at 1. CI said that she could get through because the Respondent ''hooked'' her up. GE–14, at 1. The Respondent responded, ''absolutely that needs to be about as discreet as [unintelligible].'' GE–14, at 1. The Respondent told CI to ''not take that other stuff but one at a time.'' GE–14, at 1. He said that, during Agent 1's appointment, he ''talked about headaches and pretty much left it exactly at that.'' GE–14, at 1. The Respondent told CI, ''[s]o um you got refills on that Maxalt. Um she does,'' and noted that he could not give refills ''on the other one . . ..'' GE–14, at 2.

iii. Interactions Between the Respondent and CI Between the First and Second Undercover Appointments

60. On April 1, 2015, at approximately 8:28 p.m., the Respondent and CI spoke on the phone. GE–19.[29] CI said that she spent time with Agent 1. GE–19, at 1. The Respondent asked her, ''So that all went smooth with getting your medicine and all that?'' GE–19, at 1; *see* Tr. 230–31. CI said she might need some more. GE–19, at 1. The Respondent said he was glad he could help and that it was ''just because of'' the Mississippi Board complaint that ''it just has to be straight up and clean.'' GE–19, at 1.

61. On April 2, 2015, at approximately 2:15 p.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–02_14–15–50_EDT. CI told the Respondent that Agent 1 would come back and that she ''took all'' after CI ''halved some with her.'' *Id.* CI asked the Respondent if he could ''give her a little bit more if she'd come back in.'' *Id.* at 1. The Respondent replied, ''I can do that.'' *Id.* at 2. The Respondent asked if ''she'' really had migraines. *Id.* CI said ''no'' and laughed. *Id.* The Respondent laughed too and said he was just wondering because there were a lot of refills. *Id.* The Respondent said, ''[l]ong as we don't get outta hand. Just be sure to keep 'em really hidden.'' *Id.*

62. On April 2, 2015, at approximately 3:04 p.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–02_15–04–43_EDT. CI asked the Respondent whether he could write her ''80'' if someone came in to see him. *Id.* at 1. The Respondent said he could not because it would be a red flag, and that ''40 is a pretty substantial number.'' *Id.* at 1–2. The Respondent joked that CI should tell her husband that he messed up CI's ''drug

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[26] *See* GE–16, file 2015–03–25_14–36–02_EDT.

[27] *See* GE–16, file 2015–03–26_11–18–28_EDT.

[28] The Respondent's March 27, 2015 notes in Agent 1's patient file mention photophobia. GE–59, at 4. The transcript and recording of the office visit, however, contain no mention of photophobia or any discussion of the symptoms of photophobia. GE–9–10.

[29] *See* GE–16, file 2015–04–01_20–28–54_EDT.

connection” when he filed the complaint. *Id.* at 2.

63. On April 6, 2015, at approximately 8:59 p.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–06_20–59–35_EDT. CI told the Respondent that she had talked to Agent 1, who was coming on Wednesday. *Id.* at 2. The Respondent said, “I'm glad to help her and take care of her.” *Id.* He commented that he had to follow the rules when taking care of her. *Id.* CI asked the Respondent to help her out when he saw Agent 1. *Id.* at 3. The Respondent said he would take care of Agent 1's headaches “like any other patient” and that he had to follow the rules, treating her “like anybody else.” *Id.*

64. On April 7, 2015, at approximately 1:29 p.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–07_13–29–34_EDT. CI asked the Respondent if she could attend Agent 1's appointment. *Id.* at 2. The Respondent said it was “a little bit on the risky side.” *Id.*

65. On April 7, 2015, at approximately 6:28 p.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–07_18–28–45_EDT. CI asked the Respondent if he wanted her to come with Agent 1 to her appointment the next day. *Id.* at 7. The Respondent said that he was nervous about it and had to treat Agent 1 the way he treated everyone else. *Id.* CI thanked the Respondent and said she knew he was seeing Agent 1 for her. *Id.* at 8. The Respondent said that he was treating her as a patient, and that it was dangerous. *Id.*

66. On April 7, 2015, at approximately 7:04 p.m., CI texted the Respondent and asked if he would meet her at Walmart the next day around lunch. GE–20, file 2015–05–06_141328_601–904–1188_FROM_2015–04–01_TO_2015–04–30_ALL.[30]

67. On April 8, 2015, at approximately 8:59 a.m., CI again texted the Respondent and asked him to go to Walmart on his lunch break so that she could “run into” him. GE–21, at 3. CI texted the Respondent that Agent 1 would be there and that Agent 1 knew about their relationship, but was “cool” and would “cover” for CI. GE–21, at 5–6.

68. On April 8, 2015, at approximately 10:16 a.m., the Respondent and CI spoke on the phone. GE–16, file 2015–04–08_10–16–03_EDT. The Respondent said he would love to see CI at Walmart at noon that day. *Id.* at 1. CI again said Agent 1 knew that the Respondent was CI's boyfriend. *Id.* CI said she was fat because she was not taking Adipex anymore. *Id.* at 3. The Respondent said that she worried too much and that she was beautiful. *Id.*[31] The Respondent and CI agreed to meet in Walmart that day. *Id.* at 7–8.

69. On April 8, 2015, at approximately 12:31 p.m., CI texted the Respondent and said, if he wanted to save Agent 1 some money, he could bring a prescription for her with him to Walmart. GE–21, at 8. At 12:37 p.m., the Respondent replied that he “MUST see her in the office. You know why.” GE–21, at 9.

iv. Undercover Operation at Walmart: April 8, 2015

70. On April 8, 2015, Agent 1 accompanied CI to Walmart at approximately 12:45 p.m. GE–22–23; Tr. 128–29, 133–34. The Respondent met CI in the home furnishings department. GE–22; Tr. 389. CI wore a video and audio recording device. Tr. 347–48, 389; *see* GE–22. The Respondent spoke with CI. Tr. 129; *see* GE–22. The video recording did not capture an image of the Respondent's face, and much of the recording is inaudible. GE–22.

71. The Respondent told CI to tell Agent 1 to space out her appointments more. Tr. 129–30. The Respondent said, “[w]e will be good now, so but you can't come back like every week for a prescription cause they keep up, it's like every 4 weeks.” GE–23. CI asked the Respondent how she was “supposed to last that long.” GE–23. The Respondent told her to “go buy a bottle of Vodka . . . .” GE–23.

72. At approximately 3:29 p.m., CI texted the Respondent that she really felt fat and asked him to write Agent 1 “something for that too.” GE–21, at 13.

73. Based on Findings of Fact 47 through 53, Findings of Fact 56 through 72, and the transcript at pages 91, 230, and 349, I find that, by the time the Respondent met with Agent 1 on April 8, 2015, the Respondent knew that Agent 1 was not a legitimate patient and that at least some of the medication he prescribed at that appointment would be given to and used by CI.

v. Undercover Appointment #2: April 8, 2015

74. Agent 1 had a second appointment with the Respondent that took place on April 8, 2015. GE–24–25; Tr. 102. The Respondent's nurse asked Agent 1 why she was back so soon after her first visit and if she was taking her medication correctly. GE–24; GE–25, at 1; Tr. 103. Agent 1 said she just “ran out” of medication and was taking it twice a day. GE–25, at 1.

The nurse told her that she did not need to take pain medication “every day all year long.” GE–25, at 1.

75. The Respondent met with Agent 1 and asked her what she had going on. GE–25, at 1. Agent 1 said, “Same thing. Same stuff.” GE–25, at 1. The Respondent asked if the medicine had helped. GE–25, at 1. Agent 1 said it helped “a little bit.” GE–25, at 1. The Respondent began writing almost immediately after he entered the room without conducting any sort of examination of Agent 1. GE–24–25; Tr. 103–04, 132. The appointment lasted approximately seven minutes. GE–24.

76. The Respondent and Agent 1 talked casually about boating and skiing. GE–25, at 2–3. The Respondent took out his prescription pad and wrote prescriptions for Agent 1. GE–25, at 3. The Respondent said, “[w]e need to kinda stretch this out [to] make it last a month.” GE–25, at 3.

77. The Respondent wrote two prescriptions[32] to Agent 1: one for 40 Norco, and one for Maxalt. GE–24–26; Tr. 104. The Respondent told Agent 1 that he gave her refills for Maxalt but could not for “the other.” GE–25, at 1. The Respondent again told her to “spread it out a little bit longer.” GE–25, at 2. He said that “the other ones are not really intended for . . . daily use,” but that he would “go ahead and give [her] a refill.” GE–25, at 2.

vi. Interactions Between the Respondent and CI Between the Second and Third Undercover Appointments

78. On April 8, 2015, at approximately 5:01 p.m., CI texted the Respondent and said “[t]hank u sweetheart for hooking me up again :).” GE–20, file 2015–05–06_141328_601–904–1188_FROM_2015–04–01_TO_2015–04–30_ALL.

79. On April 8, 2015, at approximately 6:15 p.m., the Respondent and CI spoke on the phone. GE–27.[33] CI asked how things went with Agent 1. GE–27, at 1. The Respondent said he thought they went okay. GE–27, at 1. The Respondent and CI discussed their encounter in Walmart. GE–27, at 3. The Respondent asked CI what Agent 1 said to CI, and she told him that Agent 1 said that they had talked about the

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[30] *Contra* Tr. 129.

[31] *See* GE–27, at 1; *contra* Tr. 225.

[32] In GE–26, the Government only provided a copy of the prescription for Norco. However, the Respondent's discussion of Maxalt, preserved in GE–24 and 25, indicates that the Respondent also prescribed Maxalt to Agent 1. Additionally, Agent 1's testimony that she received two prescriptions at this appointment was credible and uncontested. Tr. 104.

[33] *See* GE–16, file 2015–04–08_18–15–44_EDT.

Respondent's boat. GE–27, at 5. The Respondent said that he talked with Agent 1 about a boat because "we had to be in there more than ten seconds" so that his "nosy nurse" would not think, "[d]ang, why is this appointment over with in ten seconds?" GE–27, at 5.

80. On April 14, 2015, at approximately 3:48 p.m., CI texted the Respondent and asked him how many friends she could "send in ur office for 'headaches' lol?" GE–20, file 2015–04–14_15–48–52_EDT.

81. On April 14, 2015, at approximately 6:47 p.m., the Respondent and CI spoke on the phone. GE–38.[34] CI again asked the Respondent how many friends she could send to him with a headache. GE–38, at 2. The Respondent said they had to be really careful about it. *Id.* The Respondent told CI that if she had a friend who was "willing to help" her, she should not tell him about it and should just ask the friend to come by and "mention that they've got headaches." GE–38, at 2. The Respondent said he was nervous about it because he knew he was being watched. GE–38, at 2. The Respondent said that, but for CI's husband, CI could "have all the sex, drugs, and rock and roll" that she needed. GE–38, at 2. CI told the Respondent that she was "running low" and needed "some more pills or something." GE–38, at 3. The Respondent suggested she drink vodka. GE–38, at 3. CI asked if he would treat Agent 1 for a cough if Agent 1 came in for a cough, and if he would give Agent 1 cough medicine. GE–38, at 3. The Respondent said he could give her cough medicine for something legitimate, and warned CI that the state monitors drug-seeking behavior. GE–38, at 3–4. CI asked the Respondent to prescribe her a "big bottle," like he used to prescribe to her. GE–38, at 4. The Respondent said he could give her about eight ounces. GE–38, at 4. The Respondent told CI that he could not prescribe Adipex to her and explained why. GE–38, at 6. The Respondent told CI that he could help her feel happier if he did not get "busted by the . . . drug police." GE–38, at 8.

82. On April 14, 2015, at approximately 7:02 p.m., CI texted the Respondent and asked if he had any Adipex left over from a prescription to his wife. GE–20.

83. On April 15, 2015, at approximately 9:30 p.m., the Respondent and CI spoke on the phone. GE–20, 28. CI talked about being severely depressed. GE–28, file 2015–04–15_21–30–59_EDT, at 9. The Respondent talked about how CI's husband would not let her "have drugs." *Id.* at 10.

84. On April 22, 2015, at approximately 10:28 a.m., the Respondent and CI spoke on the phone. GE–20, 28. CI told the Respondent that Agent 1 and some of her friends were coming next week to see the Respondent. GE–28, file 2015–04–22_10–28–41_EDT, at 3. The Respondent warned CI that he had to be careful because it was "super serious." *Id.* CI laughed and said that they had headaches. *Id.* The Respondent told CI that prescribing frequently to people from out of town was a "big" red flag. *Id.* The Respondent said he could not "do it on any kind of regular basis." *Id.* at 4.

85. On April 22, 2015, at approximately 12:10 p.m., the Respondent texted CI that he "CANNOT do anything other than legitimate medical stuff" because it was risky and CI's husband had everyone "on high alert." GE–20. CI texted back and asked if he would see Agent 1 next week, and that Agent 1 and her friends would not "tell." GE–20. CI asked him to "write in their chart it's for migraines like u always do." GE–20. The Respondent texted back that he would see Agent 1 and treat her in a medically appropriate way. GE–20. The Respondent also texted that his usual prescription for Lorcet (40) "should last more than a month." GE–20. The Respondent texted that his feelings for CI needed to be "totally separate from [his] medical practice." GE–20.

86. On April 22, 2015, at approximately 1:03 p.m., the Respondent and CI spoke on the phone. GE–20, 28. The Respondent said that they had to be really careful because the Mississippi Board was watching him. GE–28, file 2015–04–22_13–03–23_EDT, at 1–2. He compared their situation to going to "buy drugs at a crack house." *Id.* at 2. The Respondent said everything needed to be "straight" and "above the board." *Id.* The Respondent said that his normal prescription dosage of headache medicine should last more than 30 days, and that it would raise alarm if he saw people more than once a month or every other month for headaches. *Id.* CI said that it had been a month since he saw Agent 1; the Respondent said he did not remember. *Id.* CI asked him how he got "away with it" when he was seeing her; he replied that "they weren't watching nearly as close" and that CI had legitimate headaches and he "was writing it down every time." *Id.* at 3. The Respondent said he was not giving her prescriptions "super often." *Id.* The Respondent discussed headaches, Maxalt, and Lorcet with CI. *Id.* at 3–4. CI asked the Respondent if he would see "them" next week. *Id.* at 4. The Respondent said that he would see anybody that came in to his office. *Id.* CI asked him to "write 'em Lorcet." *Id.* The Respondent said that "[i]t would even be better if I don't even know who they are" and instructed CI to not tell him their names. *Id.* The Respondent said that he treats everyone the same. *Id.* at 5. The Respondent said that he liked to be nice to Agent 1, who he identified as CI's friend. *Id.*

87. On April 22, 2015, at approximately 2:32 p.m., CI texted the Respondent, "[w]hat I wouldn't do for an aipex [sic] right now ! Omg :/." GE–20, file 2015–04–22_14–32–41_EDT.

88. On April 27, 2015, at approximately 2:45 p.m., the Respondent and CI spoke on the phone. GE–20, 28. CI said she spoke to Agent 1, who was going to see the Respondent that Wednesday. GE–20, file 2015–04–27_14–45–16_EDT. The Respondent said he would be glad to see her. *Id.* CI said that Agent 1 would give CI all of Agent 1's prescriptions. *Id.* CI said Agent 1 and Agent 2 would split Agent 2's prescriptions. GE–28, file 2015–04–27_14–45–16_EDT, at 1. The Respondent said he did not "know anything about that and [did not] want to know anything about that." *Id.* CI discussed previously taking "like 20" of the Demerol that the Respondent prescribed to her. *Id.* at 7.

89. On April 28, 2015, at approximately 8:23 p.m., the Respondent and CI spoke on the phone. GE–20, 28. CI told the Respondent to not forget that Agent 1 and Agent 2 were coming tomorrow. GE–28, file 2015–04–28_20–23–38_EDT, at 1. The Respondent acknowledged that he knew they were coming and said he would see them then. *Id.* CI told the Respondent to "[h]ook her up good. Give her some cough medicine." *Id.*

90. On April 29, 2015, at approximately 9:38 a.m., the Respondent and CI spoke on the phone. GE–20, 28, 29. CI told the Respondent not to forget that Agent 1 was coming that day. GE–29, at 7. The Respondent replied that he would not forget and would "take care of her." GE–29, at 7. CI told him to give her cough medicine. GE–29, at 7. The Respondent said he would see what he could do, but that CI was "really pushing [his] envelope." GE–29, at 7.

91. On April 29, 2015, at approximately 3:40 p.m., CI texted the Respondent that Agent 1 said that Agent 2 " 'has a cough too' if u could hook her up with some cough med . . . Please :) ." GE–39, at 5.

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[34] *See* GE–20, file 2015–04–14_18–47–34_EDT; GE–28, file 2015–04–14_18–47–34_EDT.

92. Based on Findings of Fact 47 through 53, 56 through 72, and 75 through 91, and the transcript at pages 91, 136, 230, and 349, I find that, by the time the Respondent met with Agents 1 and 2 on April 29, 2015, the Respondent knew that Agent 1 and Agent 2 were not legitimate patients and that at least some of the medications that he prescribed to them during their appointments that day would be given to and used by CI and/or shared by the Agents.

vii. Undercover Appointment #3: April 29, 2015, with Agent 1

93. Agent 1 had a third appointment with the Respondent, which occurred on April 29, 2015. GE–30–31; Tr. 111.

94. The Respondent met with Agent 1 and asked her, "Headaches for you?" GE–31, at 1. Agent 1 responded, "Yep." GE–31, at 1. The Respondent performed a brief examination of Agent 1, checking her ears and nose. GE–30–31; Tr. 112, 132. The Respondent observed that Agent 1 still had "refills on the other." GE–31, at 1.

95. Agent 1 told the Respondent that she talked on the phone with a friend of hers, who told her that she was coughing a lot and needed to get something for her cough; Agent 1 also told the Respondent that she had not paid it much attention to it. GE–31, at 1; Tr. 133, 138–39. The Respondent immediately told Agent 1 that he would give her some cough syrup. GE–30; Tr. 133, 139–40. Agent 1 was not coughing during the appointment. GE–30; Tr. 138. Agent 1 did not tell the Respondent that she had a cough. GE–30–31; Tr. 113, 132. Agent 1 did not directly request cough syrup from the Respondent. GE–30–31; Tr. 113.

96. The Respondent wrote two prescriptions to Agent 1: one for 40 Norco 10/325, and one for eight ounces of Hycodan. GE–32–33; Tr. 113.

viii. Undercover Appointment #4: April 29, 2015, with Agent 2

97. Agent 2 also had an appointment with the Respondent on April 29, 2015. GE–34–35; Tr. 143.

98. The Respondent met with Agent 2. GE–34–35; Tr. 144; *see also* GE–58 (containing the Respondent's patient file for Agent 2). The Respondent asked her what he could do for her. Agent 2 she said she had "a little headache," but noted that it had not been going on for a long time. GE–35, at 1; Tr. 144. The Respondent briefly looked into Agent 2's ears, nose, and mouth. GE–34–35; Tr. 144. The Respondent asked her a few questions about allergies, blood pressure, and smoking. GE–35, at 2. The Respondent then wrote prescriptions to Agent 2. GE–34. Meanwhile, the Respondent talked casually with Agent 2 about sports, Birmingham, and restaurants. GE–35, at 2–3.

99. The Respondent wrote two prescriptions for Agent 2: one for 40 Norco 10/325, and one for Maxalt with unlimited refills. GE–35, at 3; GE–36–37; Tr. 144.

ix. Interactions Between the Respondent and CI Between the Fourth and Fifth Undercover Appointments

100. On April 29, 2015, at approximately 1:48 p.m., the Respondent and CI spoke on the phone. GE–29, at 9. CI asked the Respondent if he had seen Agent 1. GE–29, at 9. The Respondent said he had. GE–29, at 9. CI asked him what he gave her. GE–29, at 9. The Respondent said, "appropriate medicine," and laughed. GE–29, at 9. He said that he gave her something for her headache and cough. GE–29, at 9. CI thanked the Respondent. GE–29, at 9.

101. On April 30, 2015, at approximately 9:19 a.m., the Respondent and CI spoke on the phone. GE–40; *see* GE–20, 28. CI told the Respondent that she got her medication. GE–40, at 1. The Respondent said he was "glad all that worked out." GE–40, at 1; *see* Tr. 230–31. The Respondent asked CI who Agent 2 was and if she was Agent 1's friend. GE–40, at 1. CI told the Respondent that Agent 1 gave all of hers to CI, and that Agent 1 and Agent 2 split Agent 2's prescription. GE–40, at 2. The Respondent said he was glad he could help, and that both agents were "very appropriate" because they went "through the motions." GE–40, at 2. The Respondent said that during the appointment with Agent 2, he was thinking, "I'm not mentioning [CI] and I'm not mentioning [Agent 1]." GE–40, at 2.

102. The DEA's investigation was suspended while the Respondent campaigned for political office. Tr. 78. The DEA contacted CI in October 2015 and asked her to talk to the Respondent again to try to get him to write another prescription. Tr. 358. CI said no. Tr. 358.

x. Undercover Appointment #5: October 16, 2015

103. Agent 1 had a fourth appointment with the Respondent, which took place on October 16, 2015. Tr. 78, 119. The purpose of this appointment was to refresh the investigation concerning the Respondent. Tr. 78. Upon arriving at the Respondent's clinic, the Respondent's receptionist told Agent 1 that her chart had been misplaced,[35] so Agent 1 filled out new paperwork and sat in the Respondent's waiting room. GE–42–43; Tr. 119–20, 137.

Agent 1 waited for about an hour and twenty minutes before she was called into an exam room. GE–42; Tr. 406.

104. Agent 1 met with the Respondent. GE–42; *see* GE–60 (containing Agent 1's October 16, 2015 patient file). The Respondent examined Agent 1's ears, nose, and throat. GE–60, at 4; Tr. 120, 132.[36] The Respondent asked Agent 1 what her symptoms were and what he had treated her for in the past. GE–43, at 2; Tr. 135. Agent 1 thought the Respondent was acting as though he did not know who she was. Tr. 120, 135, 452; *see* GE–42–43.

105. The Respondent discussed the most effective medication for Agent 1 to take for headaches. GE–43, at 2–3. Agent 1 asked the Respondent if he remembered Agent 2. GE–43, at 3. The Respondent stopped, thought about it, and said he did not. GE–42, 43.

106. Agent 1's recording device partially failed and did not record the last few minutes of Agent 1's appointment with the Respondent. Tr. 79, 451.

107. While the Respondent was writing prescriptions for Agent 1, she asked the Respondent if he had spoken with CI lately. Tr. 122, 135, 452–53. The Respondent paused and looked surprised, then continued writing the prescriptions and stated that he had not heard from CI lately. Tr. 122–23.

108. The Respondent wrote Agent 1 prescriptions for 30 Norco 5/325, four ounces of Hycodan, Maxalt, Zyrtec, and dexamethasone. GE–44–47, 54; Tr. 120, 126–27, 452. The Respondent discussed these prescriptions with Agent 1 during the appointment. Tr. 452–53, 455–56.

109. During this visit, Agent 1 did not say that she had a cough. GE–42–43; Tr. 126, 138–39, 454. Agent 1 only stated at the outset of the appointment that she needed the "same as before," and did not tell the Respondent that she had any specific complaints. GE–42–43; Tr. 454. The Respondent nonetheless prescribed cough syrup to Agent 1. GE–45; Tr. 139.

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[35] After the Respondent was arrested, Agent 1's original file, GE–59, was found in the Respondent's desk, along with the files for CI and CI's children. Tr. 428.

[36] The audiovisual recording of Agent 1's appointment did not record any physical examination by the Respondent during this appointment. *See* GE–42. However, because the audiovisual recording was incomplete, and because Agent 1 testified that the Respondent examined her ears, nose, and throat, I find as a matter of fact that the Respondent conducted a physical examination of Agent 1 at this appointment.

G. Search of the Respondent's Office

110. The Respondent was arrested on December 9, 2015. Tr. 427, 432. That same day, the DEA searched the Respondent's office and examined his records and patient files. Tr. 427, 432. The Respondent's office kept patient files in a general population of files. Tr. 433.

111. The DEA unlocked the Respondent's desk drawer and discovered several patient files that had not been kept in the general population of patient files. Tr. 428, 432. In the Respondent's desk, the DEA found one patient file for Agent 1, one file for CI, one file for Kid 1, and one file for Kid 2. Tr. 428; *see* GE–2, 56–57, 59.

112. The DEA found a second patient file for Agent 1 within the general population of the Respondent's patient files. Tr. 433; *see* GE–60. The DEA also found a patient file for Agent 2 in the general population of the Respondent's patient files. Tr. 434; *see* GE–58.

Additional facts required to resolve the issues in this case are included below in the Analysis section of this Recommended Decision.

ANALYSIS

To revoke a respondent's registration, the Government must prove, by a preponderance of the evidence, that the regulatory requirements for revocation are satisfied. *Steadman* v. *SEC,* 450 U.S. 91, 100–02 (1981); 21 CFR § 1301.44(e) (2015). Under 21 U.S.C. § 824(a)(4), the DEA may revoke a registrant's COR if the registrant acted in a way that renders continued registration "inconsistent with the public interest." The DEA considers the following five factors to determine whether continued registration is in the public interest:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant's] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant's] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal, or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f) (2012).

These public interest factors are considered separately. *See Robert A. Leslie, M.D.,* 68 Fed. Reg. 15227, 15230 (2003). Each factor is weighed on a case-by-case basis. *Morall* v. *DEA,* 412 F.3d 165, 173–74 (D.C. Cir. 2005). Any one factor, or combination of factors, may be decisive. *David H. Gillis, M.D.,* 58 Fed. Reg. 37507, 37508 (1993). Thus, there is no need to enter findings on each of the factors. *Hoxie* v. *DEA,* 419 F.3d 477, 482 (6th Cir. 2005). Further, there is no requirement to consider a factor in any given level of detail. *Trawick* v. *DEA,* 861 F.2d 72, 76–77 (4th Cir. 1988). When deciding whether registration is in the public interest, the totality of the circumstances must be considered. *See generally Joseph Gaudio, M.D.,* 74 Fed. Reg. 10083, 10094–95 (2009).

The Government bears the initial burden of proof, and must justify revocation by a preponderance of the evidence. *Steadman,* 450 U.S. at 100–03. If the Government makes a *prima facie* case for revocation, the burden of proof shifts to the registrant to show that revocation would be inappropriate. *Med. Shoppe–Jonesborough,* 73 Fed. Reg. 364, 387 (2008). A registrant may prevail by successfully attacking the veracity of the Government's allegations or evidence. Alternatively, a registrant may rebut the Government's *prima facie* case for revocation by accepting responsibility for wrongful behavior and by taking remedial measures to "prevent the re-occurrence of similar acts." *Jeri Hassman, M.D.,* 75 Fed. Reg. 8194, 8236 (2010). In addition, when assessing the appropriateness and extent of sanctioning, the DEA considers the egregiousness of the offenses and the DEA's interest in specific and general deterrence. *David A. Ruben, M.D.,* 78 Fed. Reg. 38363, 38385 (2013).

Factor One: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority

Neither party directly advanced an argument under Factor One. However, a substantial portion of the Respondent's post-hearing brief ("ALJ–34") argues that the DEA should give significant deference to the Mississippi Board's termination of its investigation against the Respondent. ALJ–34, at 3–6. Therefore, by inference, the Respondent advanced a theory under Factor One that his license should not be revoked because the Mississippi Board declined to take formal disciplinary action against him.

Although the Mississippi Board did not make a formal recommendation to the DEA in this matter, the DEA interprets a state licensing board's "recommendation" broadly. *See Kenneth Harold Bull, M.D.,* 78 Fed. Reg. 62666, 62672 (2013) (considering disciplinary actions taken by a state board under Factor One).[37] A state board's disciplinary actions can provide evidence of what a state licensing board would recommend. *Id.* For example, when a state board puts a registrant on probation, the DEA views the probation as a recommendation from the state board. *E.g., Tyson D. Quy, M.D.,* 78 Fed. Reg. 47412, 47417 (2013).

Here, the Mississippi Board has not revoked, suspended, or restricted the Respondent's license. GE–1, at 1; GE–3, at 1. The Mississippi Board investigated the Respondent in March 2015. *See* GE–3. This investigation was limited to reviewing an anonymous letter, interviewing the Respondent, and visiting the Respondent's office. *See* GE–3, at 1–2, 4–6. The Mississippi Board neither exonerated the Respondent nor took any formal action against him. GE–3; Tr. 184, 203. The Mississippi Board only issued a warning letter to the Respondent to conclude its investigation. GE–3, at 1. Consistent with the findings of Investigator Pohnert, the Mississippi Board warned the Respondent that doctors are only permitted to refill phentermine prescriptions if they first conduct and document medical examinations. GE–3, at 1, 5.

The fact "that a state has not acted against a registrant's medical license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest." *Carlos Gonzalez, M.D.,* 76 Fed. Reg. 63118, 63140 (2011) (citing *Patrick W. Stodola, M.D.,* 74 Fed. Reg. 20727, 20730 (2009); *Jayam Krishna-Iyer, M.D.,* 74 Fed. Reg. 459, 461 (2009)). Rather, the DEA, apart from the Mississippi Board, has its own independent responsibility to determine whether the Respondent's continued registration is in the public interest. *See Edmund Chein, M.D.,* 72 Fed. Reg. 6580, 6590 (2007), *aff'd, Chein* v. *DEA,* 533 F.3d 828 (D.C. Cir. 2008). Accordingly, the Mississippi Board's warning letter does not weigh either for or against the Respondent under Factor One.

Factors Two and Four: The Respondent's Experience in Dispensing Controlled Substances and Compliance with Applicable State, Federal, or Local Laws Relating to Controlled Substances

Allegations 1 through 5 all claim that the Respondent illegitimately prescribed controlled substances outside the course of his professional practice. *See supra* pp. 2–3. Regarding these allegations, the

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[37] *But see George R. Smith, M.D.,* 78 FR 44972, 44979 (2013) (finding that the absence of a state licensing board's direct recommendation weighs neither for nor against a respondent); *Paul Weir Battershell, N.P.,* 76 FR 44359, 44365–66 (2011) (same); *Gilbert Eugene Johnson, M.D.,* 75 FR 65663, 65666 n.3 (2010) (same).

Government endeavored to show that the Respondent knowingly diverted, or attempted to divert, controlled substances. This evidence is properly analyzed under Factors Two and Four because "[p]roof that a physician knowingly diverted controlled substances is the best evidence for assessing his experience in dispensing controlled substances, although it is also relevant in assessing his compliance with applicable laws related to controlled substances." *Syed Jawed Akhtar-Zaidi, M.D.,* 80 Fed. Reg. 42961, 42968 n.17 (2015).

Under the Controlled Substances Act ("CSA"), it is unlawful for a person to distribute controlled substances, except as authorized under the CSA. 21 U.S.C. 841(a)(1). To combat drug abuse and trafficking of controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales* v. *Raich,* 545 U.S. 1, 13 (2005). To maintain this closed regulatory system, controlled substances may only be prescribed if a DEA registrant writes a valid prescription. *Gonzalez,* 76 FR at 63141. As the Supreme Court explained, "the prescription requirement . . . ensures that patients use controlled substances under the supervision of a doctor so as to prevent addiction and recreational abuse. As a corollary, [it] also bars doctors from peddling to patients who crave the drugs for those prohibited uses." *Gonzales* v. *Oregon,* 546 U.S. 243, 274 (2006) (citing *United States* v. *Moore,* 423 U.S. 122, 135, 143 (1975)).

A controlled substance prescription is not valid unless it is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR § 1306.04(a). Federal regulations further provide that "[a]n order purporting to be a prescription issued not in the usual course of professional treatment . . . is not a prescription within the meaning and intent of [21 U.S.C. § 829] and . . . the person issuing it, shall be subject to the penalties provided for violations of [controlled substance laws]." *Id.; see* 21 U.S.C. § 842(a)(1) (establishing that, under the CSA, it is illegal for a person to distribute or dispense controlled substances without a prescription, as is required under 21 U.S.C. § 829).

Much like the federal regulations, the Mississippi Code provides that it is illegal to dispense Schedule II[38] controlled substances except upon a valid prescription written by a practitioner. Miss. Code §§ 41–29–137(a)(1), 41–29–141(1). The Mississippi Code further provides that a registrant's license may be revoked if the registrant prescribes narcotics outside of the course of legitimate professional practice, *id.* § 73–25–29(3), or if the registrant violates the Mississippi Board's administrative rules, *id.* § 73–25–29(13).

The DEA recognizes several methods to show that a registrant wrote prescriptions without a legitimate medical purpose and outside of the usual course of professional practice. *See Jack A. Danton, D.O.,* 76 FR 60900, 60901 (2011). The Respondent, however, incorrectly suggests that the Government *must* provide "medical literature" or a "medical opinion" in order to establish that a registrant acted outside the usual course of professional practice and lacked a legitimate medical purpose. ALJ–34, at 5.

Typically, the Government uses expert testimony to establish a violation of 21 CFR 1306.04(a). *T.J. McNichol, M.D.,* 77 FR 57133, 57147–48 (2012). However, "whether expert testimony is needed is necessarily dependent on the nature of the allegations and the other evidence in the case." *Beau Boshers, M.D.,* 76 FR 19401, 19402 n.4 (2011). Numerous state and federal courts have found in criminal cases, which require a higher standard of proof than is required in these proceedings, that expert testimony is not required to establish a violation of 21 U.S.C. § 841 or 21 CFR § 1306.04(a). *McNichol,* 77 FR at 57147.[39] For example, the DEA has not required expert testimony to establish a violation of 21 CFR § 1306.04(a) in cases where a prescriber engaged in drug deals,[40] where there were notable differences between patients' medical records and diagnoses,[41] and where a prescriber falsified patients' charts.[42] Simply put, whether the Government must present expert testimony is dependent on the facts of each case. *McNichol,* 77 FR at 57147–48.

In the Government's post-hearing brief ("ALJ–35"), it advanced two theories regarding how the Respondent violated 21 CFR § 1306.04(a): (1) the Respondent knowingly diverted controlled substances to CI, and (2) the Respondent violated state medical practice standards. ALJ–35, at 18–24. The Government can prove that a registrant acted outside of the usual course of professional practice and lacked a legitimate medical purpose by "providing evidence showing that [the registrant] knowingly diverted drugs." *Danton,* 76 Fed. Reg. at 60901. Additionally, the Government can prove that a registrant acted outside of the usual course of professional practice and lacked a legitimate medical purpose by providing evidence showing that the registrant violated a state medical practice standard "which has a substantial relationship to the CSA's purpose of preventing substance abuse and diversion." *Id.* Neither of these methods of proof requires the presentation of expert testimony. *Id.*

Allegation 1: Hydrocodone and Alprazolam Prescriptions to CI

In Allegation 1, the Government claimed that the Respondent prescribed hydrocodone and alprazolam to CI from February 2014 to May 2015[43] without conducting and/or documenting a physical examination, and without recording the prescriptions in CI's patient file, in violation of Mississippi Medical Board Administrative Rules Part 2640, Chapter 1, ("Mississippi Administrative Rules") 1.4, 1.11(b),[44] and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a). ALJ–1, at 2. Specifically, the Government alleged that the Respondent issued improper prescriptions to CI: (a) on May 22, 2014, for 40 units of a hydrocodone combination product; (b) on June 17, 2014, for 40 units of a hydrocodone combination product; (c) on September 11, 2014, for 40 units of a hydrocodone combination product; (d) on October 6, 2014, for 40 units of alprazolam with one refill for 40 units; (e) on October 29, 2014, for 40 units of a hydrocodone combination product; and (f) on December 4, 2014, for 180 units of a hydrocodone combination product. ALJ–1, at 2.

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[38] These sections of the Mississippi Code only apply to the Respondent's Schedule II controlled substance prescriptions. Notably, hydrocodone combination products, such as Norco and Hycodan, were re-classified by the federal government as Schedule II controlled substances on October 6, 2014. *See* Stip. 5–6. The parties made no argument, and presented no evidence, regarding the classification of hydrocodone combination products in the state of Mississippi.

[39] *E.g., United States* v. *Pellman,* 668 F.3d 918, 924 (7th Cir. 2012); *United States* v. *Armstrong,* 550 F.3d 382, 389 (5th Cir. 2008); *United States* v. *Word,* 806 F.2d 658, 663 (6th Cir. 1986); *United States* v. *Larson,* 507 F.2d 385, 387 (9th Cir. 1974); *United States* v. *Bartee,* 479 F.2d 484, 488–89 (10th Cir. 1973); *State* v. *Moody,* 393 So.2d 1212, 1215 (La. 1981).

[40] *Boshers,* 76 Fed. Reg. at 19402 n.4.

[41] *Morris W. Cochran, M.D.,* 77 Fed. Reg. 17505, 17519–20 (2011).

[42] *Robert F. Hunt, D.O.,* 75 Fed. Reg. 49995, 50003 (2010).

[43] The record does not contain any evidence that the Respondent prescribed controlled substances directly to CI in 2015. The 2015 prescriptions that the Government alluded to under Allegation 1 were the Respondent's 2015 prescriptions to Agent 1 and Agent 2. Those prescriptions are discussed at length under Allegation 4, *infra* pp. 50–58.

[44] Rule 1.11(b) requires that "[e]very written prescription delivered to a patient, or delivered to any other person on behalf of a patient, must be manually signed on the date of issuance by the physician." Miss. Code R. § 30–17–2640:1.11(b). Although the Government alleged a violation of this provision in its OSC/ISO, the Government did not advance a theory or offer evidence to establish a violation of this specific rule. I therefore find that the Government's allegation that the Respondent violated Rule 1.11(b) is **NOT SUSTAINED**.

Under the Mississippi Administrative Code, the Mississippi Board requires that a prescribing physician must:

> maintain a complete record of his or her examination, evaluation and treatment of the patient which must include documentation of the diagnosis and reason for prescribing, dispensing or administering any controlled substance; the name, dose, strength, quantity of the controlled substance and the date that the controlled substance was prescribed, dispensed or administered.

Miss. Code R. § 30–17–2640:1.4.[45] This record must "be maintained in the patient's medical records." *Id.*

Further, the Mississippi Board requires that a physician cannot prescribe a controlled substance "without a good faith prior examination and medical indication therefore." *Id.* This obligation is a continuing one; "upon *any encounter* with a patient, in order to establish proper diagnosis and regimen of treatment, a physician *must* take three steps: (a) take and record an appropriate medical history, (b) carry out an appropriate physical examination, and (c) record the results." *Id.* (emphasis added). A physician's failure to complete these three steps is conduct outside the "course of legitimate professional practice." *Id.* In fact, any violation of these rules is considered conduct outside of the course of legitimate professional practice, in violation of Section 73–25–29(3) of the Mississippi Code. Miss. Code R. § 30–17–2640:1.16.

The evidence establishes that, on four occasions, the Respondent prescribed controlled substances to CI without writing any notes about any prescriptions or examinations in CI's patient file. On May 22, 2014, the Respondent prescribed 40 units of Norco 10/325 to CI. GE–41, at 4; GE–49, at 2. On June 17, 2014, the Respondent prescribed 40 units of Norco 7.5/325[46] to CI. GE–41, at 6; GE–49, at 2. On September 11, 2014, the Respondent prescribed 40 units of Norco 10/325 to CI. GE–41, at 20; GE–49, at 2. On December 4, 2014, the Respondent prescribed 180 units, or six ounces, of Hycodan to CI.[47] GE–41, at 28; GE–49, at 1. None of these four prescriptions were recorded in CI's medical file. *See* GE–2, at 12–13. The Respondent did not document a diagnosis or reason for prescribing to CI on any of these dates. The Respondent did not write the names, doses, strengths, or quantities of these prescriptions to CI in CI's medical record. The Respondent did not record the dates of these prescriptions in CI's medical record. The Respondent did not record any notes in CI's medical record about any physical examinations on these dates.

Because of the complete absence of this required information in CI's patient file, the prescriptions that the Respondent wrote to CI on these four dates were improper under Mississippi Administrative Rule 1.4. The Government's allegations that these four prescriptions to CI violated Mississippi Administrative Rule 1.4 are **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government. Because these prescriptions violated Mississippi Administrative Rule 1.4, these prescriptions were issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Further, there is no evidence that the Respondent even saw CI on May 22, June 17, September 11, or December 4 of 2014. Even absent expert testimony, the DEA has held that a prescriber does not act in the usual course of professional practice if the prescriber writes prescriptions to a patient without first seeing the patient. *Armando B. Figueroa, M.D.*, 73 Fed. Reg. 40380, 40381–82 (2008). Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) on these four occasions are **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

On October 6, 2014, the Respondent prescribed 40 units of alprazolam 1 mg, with one refill, to CI. GE–41, at 22; GE–49, at 1. In CI's medical file, near a date stamp reading September 2, 2014, the Respondent noted "Xanax 1mg (#40, 1)," but did not write any justification for this prescription, as is required by Mississippi Administrative Rule 1.4. *See* GE–2, at 12–13. The Respondent did not write any notes anywhere in CI's patient file about a diagnosis of anxiety or any of CI's alleged symptoms. *See* GE–2, at 12–13. Additionally, CI's testimony and her PMP report indicate that, although CI's psychiatrist prescribed a smaller dosage of alprazolam to her, the Respondent increased CI's dosage without any noted justification. GE–49, at 1; Tr. 225–26, 295, 304; *see* GE–2 (failing to justify an increased dosage of alprazolam); *see also* GE–2, at 21 (documenting that another registrant prescribed 7 units of alprazolam ER 0.5 mg to CI on September 30, 2014, and that the Respondent then prescribed 40 units of alprazolam 1 mg on October 6, 2014). Because the Respondent never documented a reason for prescribing alprazolam to CI in her patient file, the Government's allegation that the October 6, 2014 prescription violated Mississippi Administrative Rule 1.4 is **SUSTAINED** by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government. Because this prescription violated Mississippi Administrative Rule 1.4, this prescription was issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) by issuing the October 6, 2014 prescription are also SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

The Government also alleged that the Respondent prescribed 40 units of a hydrocodone product to CI on October 29, 2014. ALJ–1, at 2. Although this alleged prescription is noted on CI's PMP report, *see* GE–49, as Government counsel stated, "PMPs are not without their flaws" and are not "necessarily accurate." Tr. 302–03. The Government offered testimony from CI related to this alleged prescription. Tr. 369–70. CI was presented with a copy of this alleged prescription, which she reviewed. Tr. 369–70. At the hearing, CI did not testify about the prescription from her personal recollection; she only looked at and read off of the copy of the prescription presented to her. Tr. 369–70. I do not find that CI's testimony proved the existence of the October 29 prescription. This copy of the prescription was not offered into evidence.[48] In sum, the Government failed to offer substantial evidence that the Respondent did, in fact, prescribe hydrocodone to CI on October 29, 2014 outside of the course of his professional practice. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rules 1.4 and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) by issuing an October 29, 2014 prescription are **NOT SUSTAINED**.

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[45] I find that the documentation requirements of Mississippi Administrative Rule 1.4 share a substantial relationship with the CSA's purpose of preventing drug abuse and diversion.

[46] Originally, the Government alleged that the Respondent prescribed Norco 10/325 on June 17, 2014. *See* ALJ–1, at 2. However, as the Government correctly noted in its post-hearing brief, the Respondent prescribed Norco 7.5/325 on June 17, 2014. ALJ–35, at 6 n.1; *see* GE–41, at 6.

[47] The record reflects some confusion concerning the date of this prescription. GE–41, at 21, indicates it was written on December 3, 2014, while GE–49, at 1, indicates it was written on December 4, 2014. *See supra* note 19. Regardless of the one day variance, the analysis is the same.

Beyond the above-mentioned specific prescribing events, the Government provided ample evidence that, throughout 2014, the Respondent prescribed controlled substances to CI outside of the usual course of his professional practice and without a legitimate medical purpose. The DEA has held, even without the benefit of expert testimony, that a controlled substance prescription based on a patient's request "rather than the result of the application of the physician's medical judgment" lacks a medical purpose. *Robert M. Golden, M.D.,* 61 Fed. Reg. 24808, 24812 (1996) (citing *Robert L. Dougherty, Jr., M.D.,* 60 Fed. Reg. 55047 (1995); *Harland J. Borcherding, D.O.,* 60 Fed. Reg. 28796 (1995)). Likewise, the Mississippi Administrative Rules state that a prescriber lacks good faith when he "permit[s] the patient to name the drug desired" or "dispens[es] drugs to patients having no medical need, when the physician knew or should have known that the patients were addicts." Miss. Code R. § 30–17–2640:1.4.

It is true that, at times, the Respondent intended to treat CI's medical conditions. GE–2, at 12–13; Tr. 215, 277–78, 287, 321. However, even if the Respondent subjectively intended to provide legitimate medical treatment to CI, "[t]he appropriate focus is not on the subjective intent of the doctor, but rather . . . whether the physician prescribe[d] medicine 'in accordance with [the accepted] standard of medical practice.' " *United States* v. *Merrill,* 513 F.3d 1293, 1306 (11th Cir. 2008) (quoting *United States* v. *Moore,* 423 U.S. 122, 139 (1975)). The Respondent's failure to perform and document physical examinations of CI, and his failure to document his prescriptions to CI, constitutes a significant failure to comply with Mississippi medical standards, regardless of the Respondent's subjective intent.

Here, CI took Norco daily and recreationally, and the Respondent gave prescriptions to CI upon her request. Tr. 297–99. The Respondent gave prescriptions to CI at her house, at her children's appointments, and in the garden section of Walmart. Tr. 26, 217–20. The Respondent did not provide CI with a diagnosis or perform physical examinations before giving these prescriptions to CI. *See* Tr. 217–18; *see also* GE–2, at 12–13.

Importantly, the Respondent only made three entries in CI's patient file in 2014, on February 21, April 21, and September 2, and he made no entries in CI's patient chart in 2015. *See* GE–2, at 12–13. Neither party presented any standard to evaluate the adequacy of the patient file entries.[49] Assuming that the file entries on those dates are adequate, under Mississippi Administrative Rule 1.4, *any* prescriptions that the Respondent issued to CI in 2014, other than on February 21, April 21, and September 2, were issued outside of the Respondent's professional practice. CI's PMP report indicates that CI may have filled prescriptions written by the Respondent on 13 dates in 2014.[50] I do not find that the PMP report, standing alone, constitutes substantial evidence that these prescriptions existed, as discussed *supra.* However, CI's credible, confident, and uncontested testimony that she simply requested prescriptions from the Respondent "for fun," and that he would give them to her, considered in conjunction with the PMP report, constitutes substantial evidence that the Respondent prescribed controlled substances to CI in 2014 based on CI's request rather than in the proper exercise of sound medical judgment. On these grounds, the Government's allegations that the Respondent violated Mississippi Administrative Rules 1.4 and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) are also **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

Allegation 2: Phentermine Prescriptions to CI

In Allegation 2, Government claimed that the Respondent prescribed phentermine[51] to CI without adequate documentation, in violation of Mississippi Administrative Rule 1.5, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a). ALJ–1, at 3. The Government specifically alleged that this inappropriate prescribing occurred on four occasions in 2014: April 9, for 30 dosage units; May 19, for 30 dosage units with one refill; July 24, for 30 dosage units; and September 8, for 30 dosage units with two refills. ALJ–1, at 3.

The administration of weight loss medication is regulated by state medical standards. *See generally Wesley G. Harline, M.D.,* 65 Fed. Reg. 5665 (2000) (discussing, at length, general practice and state medical standards for legitimately prescribing controlled substances for weight loss). The Mississippi Board has a special standard of care for practitioners who prescribe diet medication. *See* Miss. Code R. § 30–17–2640:1.5; *see also* GE–8; Tr. 171–72. Specifically, Rule 1.5 requires a doctor prescribing weight loss drugs to: (1) only prescribe adjunctively with caloric restriction; (2) conduct and thoroughly record an initial comprehensive evaluation; (3) record a thorough patient history and physical exam; (4) conduct an in-person re-evaluation of the patient once every 30 days, recording the patient's weight, BMI, blood pressure, pulse, and the results of all tests to monitor adverse effects of the medication; and (5) maintain records about the patient's weight loss efforts, dedication, responses, contraindications, and adverse effects during treatment. Miss. Code R. § 30–17–2640:1.5. The patient's history and physical exam must, *at a minimum,* document:

1. Past medical history, past surgical history, social history, family history, weight history, dietary history, gynecological (GYN) history if female, review of systems, allergies and medications.

2. Height, weight, Body Mass Index (BMI), blood pressure, pulse, % body fat or waist circumference/weight hip ratio, HEENT, chest, heart, abdomen, extremities.

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[48] *See supra* note 20.

[49] CI's patient file is not entirely legible. *See* GE–2, at 12–13. The February 21, 2014 entry reads: "HC 7.5/325 (#40, 1)—may be picked up at desk." GE–2, at 12. The April 21, 2014 entry reads: "Headaches ? 'Sinuses' Motion sickness Occasional vertigo Ears clear OC/OP clear Nose mildly inflamed CT → clear and thickening in L NF duct Rx Maxalt (one given) HC 10/325 (#40) (refill)." GE–2, at 12. The September 2, 2014 entry reads: "Lexapro Maxalt prn has anxiety c̄ migraines Migraine—usually responsive to Maxalt, now c̄ brea[illegible] Ears clean; [illegible] in ® EAC @[illegible] Nose clear OC/OP clear Counseled [illegible] Rx Zofran Demerol 50 (#30) HC 10/325 (#40, 1) Phentermine (refilled) Xanax 1mg (#40, 1)." GE–2, at 12. These three notations are the only entries in the Respondent's patient file for CI during 2014.

[50] Specifically, these dates are as follows: February 21, April 9, May 19, May 22, June 17, July 19, July 24, September 2, September 8, September 11, October 6, October 29, and December 4. *See* GE–2, at 21–23; GE–49, at 1–3.

[51] Phentermine, or Adipex, is a Schedule IV controlled substance. *See* Stip. 8.

3. Appropriate testing related to medical weight loss . . . .

Id.

The Government presented evidence that the Respondent wrote four prescriptions for phentermine to CI. On April 9, 2014, the Respondent prescribed 30 units of Adipex 37.5 to CI. GE–7, at 1–2; GE–49, at 2. On May 19, 2014, the Respondent prescribed 30 units of Adipex 37.5, with one refill to CI. GE–7, at 3–4; GE–41, at 2–3; GE–49, at 2. On July 24, 2014, the Respondent prescribed 30 units of Adipex 37.5 to CI. GE–7, at 5–6; GE–41, at 12–13; GE–49, at 2. On September 8, 2014, the Respondent prescribed 30 units of phentermine 37.5 with two refills to CI. GE–7, at 7–8; GE–41, at 18–19; GE–49, at 2. During 2014, CI filled these prescriptions seven times. GE–49, at 1–2.

In the administrative record, there are only four notations in the Respondent's files related to phentermine, Adipex, or weight loss prescriptions. The first mention of phentermine is in the Respondent's patient file for Kid 1 near a date stamp reading February 4, 2014. GE–57, at 6; Tr. 286. That note reads, "Mother has migraines ? in children May call in Rx if needed. Discussed phentermine c̄ mother May consider this as well." GE–57, at 6. The second time phentermine was mentioned was in a March 19, 2014 entry in Kid 1's patient file. That note reads, "Discussed [illegible] medications c̄ mother Rx [illegible] Phentermine 37.5." GE–57, at 5; Tr. 286. The third mention of phentermine, and the first in the Respondent's patient file for CI, is dated July 18, 2014. GE–2, at 15. This third mention is on a patient telephone request form, which indicated that CI called the Respondent to ask about a refill of "phentermine 37.5 (#30, 2)" for her to "pick up at front." GE–2, at 15. The final mention of phentermine, and the only one contained in the Respondent's treatment notes of CI, is dated September 2, 2014. GE–2, at 12. This last entry simply reads, "Phentermine (refilled)." GE–2, at 12.

Accordingly, while prescribing phentermine to CI on April 9, May 19, July 24, and September 8, the Respondent completely failed to comply with the requirements of Mississippi Administrative Rule 1.5. The Respondent never prescribed phentermine adjunctively with caloric restriction. He never conducted and recorded an initial comprehensive evaluation. He never recorded a thorough patient history or physical examination. He never conducted an in-person re-evaluation of CI once every 30 days. He never recorded CI's, BMI, blood pressure, pulse, past medical history, social history, family history, dietary history, gynecological history, height, weight, or body measurements. He did not document CI's efforts to lose weight or note her response to treatment.

A prescriber lacks good faith if he prescribes controlled substances to a patient who the prescriber knew or should have known had no legitimate medical need for the controlled substances prescribed. Miss. Code R. § 30–17–2640:1.4. It is concerning that the Respondent wholly failed to document any justification whatsoever for CI's supposed need for weight loss medication. During 2014, CI went from 135 pounds down to 121 pounds. Tr. 224. At the hearing, CI presented with a slender body type. After observing CI's appearance, I find it difficult to comprehend, from even a layman's perspective, how the Respondent could have possibly believed that CI had a high enough BMI[52] to justify the administration of weight loss medication.

The Respondent displayed a complete disregard for Mississippi's weight loss prescription requirements. He prescribed weight loss drugs to CI without any documented medical justification. GE–2, at 12–13. "[W]here a medical record contains no findings that support a diagnosis, . . . expert testimony is not necessary to conclude that a prescription lacked a legitimate medical purpose." *McNichol,* 77 Fed. Reg. at 57151 (citations omitted). Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.5, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a), by prescribing phentermine to CI on April 9, May 19, July 24, and September 8 of 2014 are **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

The Respondent argued in his post-hearing brief that, after receiving the Mississippi Board's warning letter, he refused to prescribe weight loss medication to an undercover agent. ALJ–34, at 6. The Respondent argued that this refusal showed that he "came promptly into conformity" with Mississippi's weight loss medication prescribing standards. ALJ–34, at 6. However, even if the Respondent took remedial measures, those measures, standing alone, cannot rebut the Government's *prima facie* case for revocation unless the Respondent also accepted responsibility for his actions. *See Michael S. Moore, M.D.,* 76 Fed. Reg. 45867, 45868 (2011); *Hassman,* 75 Fed. Reg. at 8236. The Respondent did not testify and did not accept responsibility. Accordingly, the Respondent failed to rebut the Government's *prima facie* case for revocation based upon his violation of state regulations that detail the requirements for prescribing weight loss medication.

Allegation 3: Prescribing to CI's Children: Physical Examinations, Propriety of Prescriptions, and True Intended Recipient

In Allegation 3, the Government claimed that, from February 7 to November 19 of 2014, the Respondent prescribed hydrocodone products to CI's children without conducting examinations, and that the prescriptions were for CI's personal use, in violation of Mississippi Administrative Rules 1.4, 1.10, 1.11(b),[53] and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) and 1306.05(a). ALJ–1, at 2–3. Mississippi Administrative Rule 1.10 requires that a prescription for a controlled substance contain "the complete name and address of the patient to whom the physician is prescribing the controlled substance." Miss. Code R. § 30–17–2640:1.10. Likewise, 21 CFR § 1306.05(a) requires that a controlled substance prescription must "bear the full name and address of the patient."

Additionally, the Government alleged that the Respondent prescribed hydrocodone-homatropine ("cough") syrup, or Hycodan, to CI's children, who were under the age of six, even though cough syrup is not recommended for children under the age of six because of a risk of death. ALJ–1, at 3. The Government alleged that the Respondent prescribed adult dosages of this cough syrup to these children, even though the recommended dosage for children aged six to eleven is half of the adult dosage. ALJ–1, at 2–3.

The Government further alleged that the Respondent issued the following improper prescriptions for hydrocodone combination products to CI's children in

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[52] *See* Miss. Code R. § 30–17–2640:1.5(A)(4) (requiring generally a BMI of greater than 30.0 in a normal, otherwise healthy patient to justify prescribing weight loss drugs); *see also Minnix* v. *Colvin,* No. 2:12CV00038, 2014 WL 618688, at *3 n.3 (W.D. Va. Feb. 18, 2014) (defining a BMI of 30 or higher as obesity) (citing Nat'l Inst. of Health, *Calculate Your Body Mass Index, http://www.nhlbi.nih.gov/guidelines/obesity/BMI/bmicalc.htm* (last visited May 18, 2016)).

[53] For the reasons previously discussed, *supra* note 44, the Government's allegation that the Respondent violated Mississippi Administrative Rule 1.11(b) is NOT SUSTAINED.

2014: (a) to Kid 2 on February 7, for 150 dosage units, with one refill; (b) to Kid 1 on June 17, for 180 dosage units, with one refill; (c) to Kid 2 on July 23, for 480 dosage units; (d) to Kid 2 on September 2, for 120 dosage units; (e) to Kid 2 on November 3, for 180 dosage units; and (f) to Kid 1 on November 19, for 115 dosage units. ALJ–1, at 2–3.

A. The February 7 Prescription

On February 7, 2014, the Respondent wrote a prescription for 240 units of Hycodan to Kid 2. GE–50, at 1; GE–55, at 1–2. The Respondent's medical file for Kid 2 appeared to contain a notation from 2014, possibly from February 7, documenting a Hycodan prescription. *See* GE–56, at 4. The copy of the medical file partially cut off this notation because it was at the bottom of a copied page. *See* GE–56, at 4. The only legible part of the notation appears to read, "Hycodan (8 oz, 2 refills) to Brookhaven Walmart." *See* GE–56 at 4.

CI testified that the Respondent did not examine Kid 2 before prescribing cough syrup to her in February. Tr. 217, 251. The Respondent's patient file for Kid 2 does not include any notes about any physical examination on that date. The Respondent did not document a diagnosis for Kid 2 on that date. Because this required information was not recorded prior to prescribing controlled substances to Kid 2, the Government's allegation that the Respondent violated Mississippi Administrative Rule 1.4 by failing to conduct a physical examination of Kid 2 is SUSTAINED by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government. Because this prescription violated Mississippi Administrative Rule 1.4, it was issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) on February 7, 2014, are also **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

Just 15 days before the February 7, 2014 prescription, the Respondent prescribed 120 units (or 24 days' worth) of Hycodan syrup to Kid 2. *See* GE–50, at 1; GE–56, at 4. Thus, Kid 2 still should have had approximately nine days of Hycodan syrup remaining from her last prescription and should not have needed additional Hycodan syrup on February 7, much less double the original dosage. *See* GE–50, at 1 (showing that the January 24, 2014 prescription was a 24-day supply). CI discussed the real reason that the Respondent wrote this prescription. CI testified that, in February 2014, the Respondent prescribed a big bottle of cough syrup to Kid 2 so that CI could drink it as well, even though the Respondent knew that CI did not have a cough. Tr. 216–17, 250–53, 259, 268, 273. While Kid 2 did have a cough at that time, Tr. 250–51, 253–55, I give full credit to CI's testimony that the Respondent knew that CI intended to consume some of Kid 2's Hycodan prescription. Considering the timing of the February 7 prescription and its large dosage, I find, based on a totality of the circumstances, that a preponderance of evidence supports the conclusion that the Respondent knew that CI would consume at least part of Kid 2's February 7, 2014 prescription. It is a violation of 21 CFR § 1306.05 for a registrant to prescribe controlled substances to a patient knowing that someone other than the patient named on the prescription would receive the medication. *Golden,* 61 FR at 24811. Therefore, the Government's allegations that the February 7, 2014 prescription violated Mississippi Administrative Rule 1.10 and 21 CFR § 1306.05(a) are **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

B. The June 17, July 23, and November 19 Prescriptions

The Respondent wrote three prescriptions to CI's children without recording the prescriptions in the children's medical records. First, on June 17, 2014, the Respondent wrote a prescription for six ounces (or 180 units) of Hycodan syrup to Kid 1. GE–51, at 1; GE–55, at 3–4. The Respondent's patient file for Kid 1 does not contain any notes dated on or about[54] June 17, 2014. *See* GE–57. The Respondent did not document a diagnosis for Kid 1 at this time. Then, on July 23, 2014, the Respondent wrote a prescription for 16 ounces (or 480 units) of Hycet liquid to Kid 2. GE–50, at 1; GE–55, at 5–6. The Respondent's patient file for Kid 2 does not contain any notes dated on or about July 23, 2014. *See* GE–56. Finally, on November 19, 2014, the Respondent wrote a prescription for eight ounces (or 115 units) of Hycodan for Kid 1. GE–51, at 1; GE–55, at 11. The Respondent's patient file for Kid 1 does not contain any notes on or about November 19, 2014. *See* GE–56.

The Respondent did not write the name, dose, strength, or quantity of any of these prescriptions in the medical records of CI's children. The Respondent did not record the dates of the prescriptions or the reasons for the prescriptions. The Respondent did not record any notes about any physical examinations on these dates. There is no evidence in the record before me indicating that the Respondent ever saw CI's children on the dates that he wrote these prescriptions to them. Even absent any expert testimony, failure to see a patient before prescribing medications to the patient is outside of the legitimate practice of medicine. *Figueroa,* 73 FR at 40381. Therefore, the Government's allegations that the June 17, 2014, and November 19, 2014 prescriptions to Kid 1, and July 23, 2014 prescription to Kid 2, violated Mississippi Administrative Rule 1.4 are SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government. Because these prescriptions violated Mississippi Administrative Rule 1.4, they were issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) by issuing the June 17, July 23, and November 19 prescriptions are SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

The Government further alleged that these prescriptions were issued for CI's personal use. The Government bears the burden of proof on this point. The administrative record in this case supports the conclusion that the Government established, by a preponderance of the evidence, that the Respondent knew that CI would consume at least part of the cough syrup he prescribed to CI's children on June 17, July 23, and November 19. In this regard, CI testified that: (1) she would tell the Respondent when her child would have a cough; (2) she never brought her children to see the Respondent regarding a cough; (3) she requested cough syrup from the Respondent because she enjoyed drinking it; and (4) she would request a big bottle of cough syrup. Tr. 220, 265–66, 273. In addition, the administrative record supports CI's testimony that she did not bring her children to see the Respondent regarding a cough, as evidenced by their medical charts. GE–

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[54] Although the Respondent's patient file for Kid 1 includes notes from examinations on March 19, 2014, and June 9, 2014, the notes next to these dates do not contain any notations about a Hycodan prescription. *See* GE–57.

56, at 2–4; GE–57, at 5–6. I find that CI's testimony, when considered cumulatively and in conjunction with other evidence of record, establishes that, at the time the Respondent wrote the June 17, July 23, and November 19 prescriptions, he knew that CI would drink at least some of the cough syrup, though there was no medical reason for her to do so. Therefore, the Government's allegations that these three prescriptions violated Mississippi Administrative Rule 1.10 and 21 CFR § 1306.05(a) are SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

C. The September 2 and November 3 Prescriptions

On September 2, 2014, the Respondent wrote a prescription for four ounces (or 120 units) of Hycodan for Kid 2. GE–50, at 1; GE–55, at 7–8. The Respondent's patient file for Kid 2 included some notes dated September 2, 2014. GE–56, at 3. These notes stated, "URI Ears clear Nose, OC/OP mildly inflamed Lungs clear Rx [illegible] 15 Hycodan." GE–56, at 3. Because these notes indicate that the Respondent examined Kid 2, and because the Government did not enter any evidence contesting the accuracy of these notes, I find that the Government failed to show by substantial evidence that the Respondent did not conduct a physical examination of Kid 2 on September 2, and the Government's allegation to that effect is NOT SUSTAINED. However, Kid 2's medical record did not include any diagnosis or reason for prescribing Hycodan to Kid 2, as required by Mississippi Administrative Rule 1.4. Additionally, the medical record did not clearly include the dose, strength, or quantity of Hycodan prescribed to Kid 2, as required by Mississippi Administrative Rule 1.4. Because the medical record did not contain this information, the Government's allegation that the September 2, 2014 prescription to Kid 2 violated Mississippi Administrative Rule 1.4 is SUSTAINED by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government. Because this prescription violated Mississippi Administrative Rule 1.4, it was issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) by issuing the September 2, 2014 prescription are also SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

Similarly, on November 3, 2014, the Respondent wrote a prescription for six ounces (or 180 units) of Hycodan for Kid 2. GE–50, at 1; GE–55, at 9–10. The Respondent wrote a note near a date stamp reading November 4, 2014, in Kid 2's file. GE–56, at 2. This note said, "[illegible] 5 problems Rx Hycodan (6 oz) (requested)." GE–56, at 2. The medical record did not include documentation of a diagnosis and reason for prescribing controlled substances, other than the fact that it was "requested." Moreover, the medical record did not include the dosage or strength of the Hycodan prescribed, as is required by Mississippi Administrative Rule 1.4. Further, the notes near the November 3, 2014 date stamp did not indicate that the Respondent conducted any examination prior to prescribing Hycodan to Kid 2, as is required by Mississippi Administrative Rule 1.4. Therefore, the Government's allegation that the November 3, 2014 prescription to Kid 2 violated Mississippi Administrative Rule 1.4 is SUSTAINED by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government. Because this prescription violated Mississippi Administrative Rule 1.4, it was issued outside of the course of the Respondent's legitimate professional practice under Mississippi Administrative Rule 1.16. Therefore, the Government's allegations that the Respondent violated Mississippi Administrative Rule 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR § 1306.04(a) by issuing the November 3, 2014 prescription are also SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

The Government also alleged that the September 2 and November 3 prescriptions were issued for CI's personal use. The Government bears the burden of proof on this point. The administrative record in this case supports the conclusion that the Government established, by a preponderance of the evidence, that the Respondent knew that CI would consume at least part of the cough syrup he prescribed to CI's children on September 2 and November 3. In this regard, CI testified that: (1) she would tell the Respondent when her child would have a cough; (2) she never brought her children to see the Respondent regarding a cough; (3) she requested cough syrup from the Respondent because she enjoyed drinking it; and (4) she would request a big bottle of cough syrup. Tr. 220, 266, 273. In addition, the administrative record supports CI's testimony that she did not bring her children to see the Respondent regarding a cough, as evidenced by their medical charts. GE–56, at 2–4; GE–57, at 5–6. I find that CI's testimony, when considered cumulatively and in conjunction with other evidence of record, establishes that, at the time the Respondent wrote the September 2 and November 3 prescriptions, he knew that CI would drink at least some of the cough syrup, though there was no medical reason for her to do so. Therefore, the Government's allegations that these two prescriptions violated Mississippi Administrative Rule 1.10 and 21 CFR 1306.05(a) are SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

D. Dangerous Prescriptions

The Government alleged that the Respondent prescribed cough syrup to CI's children, who were under the age of six, even though cough syrup is not recommended for children under the age of six because of a risk of death. ALJ–1, at 3. The Government also alleged that the Respondent prescribed adult dosages of cough syrup to these children, even though the recommended dosage for children aged six to eleven is half of the adult dosage. ALJ–1, at 2–3.

There is no evidence on the record before me[55] that indicates that it is improper to prescribe cough syrup to children. There is no evidence on the record before me that indicates that the dosages of cough syrup that the Respondent prescribed to CI's children were improper dosages. The Government did not offer an authentic, well-founded medical opinion that the quantities and types of prescriptions to CI's children were improper. The Government had the burden of proving that the prescriptions were unlawful. *See Ruben*, 78 FR at 38384. The Government failed to meet this burden. Accordingly, the Government's allegations regarding the propriety of the Respondent's prescriptions to CI's children are **NOT SUSTAINED**.

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[55] The Government offered into evidence three printouts from Web sites, allegedly obtained from the FDA's Web site, WebMD, and Drugs.com. *See* Gov't Proposed Exs. 4–6. Upon the Respondent's timely objection, I rejected these three exhibits because they were improper opinion testimony, lacked adequate foundation, and were not properly authenticated. *See* Tr. 418–26.

Allegation 4: Fraudulent Prescriptions for CI through Undercover Agents[56]

In Allegation 4, the Government claimed that, on five occasions between March and October 2015, the Respondent prescribed controlled substances to undercover agents when he knew or should have known that the agents' prescription requests were fraudulent, in violation of 21 U.S.C. §§ 841(a) and 842(a) and 21 CFR § 1306.04(a). ALJ–1, at 3. The Government alleged that the Respondent wrote seven hydrocodone prescriptions on five occasions to undercover agents, for 190 total dosage units of hydrocodone tablets and 72 total dosage units of hydrocodone syrup. ALJ–1, at 11. The Government alleged that, on four of those occasions, the Respondent knew that CI would receive a portion of the prescribed medications. ALJ–1, at 3–4.

A. Undercover Appointments 1 through 4

The evidence against the Respondent regarding the first four undercover appointments is significant, conclusive, and uncontested.

The Respondent compared his diversion of drugs to CI with going to "buy drugs at a crack house." GE–28, file 2015–04–22_13–03–23_EDT, at 2. In some sense, this was an apt description. Whenever CI asked the Respondent for drugs, he would attempt to convey them to her. Prior to each of the first four undercover appointments, CI clearly and repeatedly asked the Respondent for controlled substances.[57] CI specifically named certain controlled substances that she wanted the Respondent to prescribe to Agent 1 and Agent 2 to divert to her.[58] Although the Respondent wanted to be ignorant about the identities of CI's "friends,"[59] the Respondent knew that Agent 1 and Agent 2 were "friends" of CI[60] and that they would give CI at least some of the drugs he prescribed to them.[61] The Respondent had reason to know that Agent 1 and Agent 2 did not legitimately need medication for themselves.[62] The Respondent had reason to know that Agent 1, Agent 2, and CI were splitting their prescriptions.[63] Therefore, based on the communications exchanged between the Respondent and CI, I find that the Respondent knew that Agent 1 and Agent 2 were "not seeking treatment for a legitimate medical condition but [were] engaged in . . . diversion." *See McNichol,* 77 FR at 57148. Despite circumstances that plainly and unambiguously indicated diversion, the Respondent nonetheless prescribed drugs to Agent 1 and Agent 2 during the first four undercover appointments.

Even beyond this, the Respondent took extra efforts to facilitate the diversion of drugs to CI. The Respondent discussed the scheduling of Agent 1 and Agent 2's appointments with CI, and CI reminded him about the timing of those appointments.[64] The Respondent asked CI to tell her friends to pretend they had headaches and act like legitimate patients.[65] After the third and fourth undercover appointments, the Respondent praised Agent 1 and Agent 2 for acting very appropriately by going "through the motions." GE–40, at 2. After each of the first four appointments, CI told the Respondent that she had received the drugs prescribed to Agent 1 and Agent 2; in response, the Respondent stated that he was happy to help get drugs to CI.[66]

It is true that the Respondent conducted appointments with Agents 1 and 2, and wrote notes in their medical files. In that aspect, this case is similar to *Robert F. Hunt, D.O.,* 75 FR 49995 (2010). Dr. Hunt had said that he wrote information on a patient's chart "just to cover [his] ass." *Id.* at 50003. The DEA held that this statement made it "clear that [Dr. Hunt] knew that he lacked a legitimate medical purpose for prescribing" controlled substances. *Id.* Similarly, although the Respondent conducted appointments with Agents 1 and 2 and wrote notes in their medical files, the Respondent's statements to CI before and after each of the first four appointments made it clear that the Respondent was unquestionably prescribing controlled substances to Agents 1 and 2 to intentionally divert drugs to CI. His statements also make clear that the records he was keeping concerning Agents 1 and 2 were merely to keep the Mississippi Board investigators at bay. *E.g.,* GE–18, at 3.

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[56] In its post-hearing brief, the Government argued that this conduct should be analyzed under Factor Five. ALJ–35, at 21–24. However, in the Government's OSC/ISO and its presentation of evidence at the hearing, the Government made a strong argument that the Respondent's prescriptions to the undercover agents violated state and federal laws, and were acts of knowing diversion which reflected poorly on the Respondent's experience in dispensing controlled substances. Therefore, analysis of this conduct under Factors Two and Four is appropriate.

[57] GE–16, file 2015–03–16_18–51–48_EDT, at 20–21, 24–26 (expressing that CI was seeking drugs before the first undercover appointment); GE–16, file 2015–03–18_11–03–33_EDT, at 2 (same); GE–17, at 4 (same); *see* GE–16, file 2015–04–02_14–15–50_EDT, at 1 (expressing that CI was seeking drugs before the second undercover appointment, and indicating that she had taken all of the drugs from the first appointment too quickly); *see also* GE–28, file 2015–04–13_20–26–31_EDT, at 7 (expressing that CI was seeking more drugs before the third and fourth undercover appointments); GE–28, file 2015–04–28_20–23–38_EDT, at 1 (same); GE–38, at 2–3 (same).

[58] GE–16, file 2015–03–17_13–07–36_EDT, at 4 (asking for Lorcet/Norco before the first undercover appointment); GE–17, at 3 (same); GE–18, at 3 (asking for Norco before the first undercover appointment); *see* GE–16, file 2015–04–02_15–04–43_EDT, at 1–2 (asking for a double dosage, presumably of Norco, before the second undercover appointment); *see also* GE–28, file 2015–04–28_20–23–38_EDT, at 1 (asking for cough medicine before the third and fourth undercover appointments); GE–29, at 7 (same); GE–38, at 3–4 (asking for a "big bottle" of cough syrup before the third and fourth undercover appointments); GE–39, at 5 (asking for cough medicine before the third and fourth undercover appointments).

[59] GE–28, file 2015–04–22_13–03–23_EDT, at 4–5 (expressing his desire to remain ignorant before the third and fourth undercover appointments); GE–28, file 2015–04–27_14–45–16_EDT, at 1 (same); GE–38, at 2 (same). The Respondent even stated at one point, "if [Agent 1 is] coming in for what I think she's coming in, tell her not to tell me that. That needs to be your secret. I don't wanna know that. She needs to have a headache and I will treat her for a headache, and so don't mind giving her prescriptions to treat a headache." GE–17, at 7.

[60] GE–16, file 2015–04–07_13–29–34_EDT, at 2 (discussing CI accompanying Agent 1 to her appointment); GE–16, file 2015–04–07_18–28–45_EDT, at 7–8 (same); GE–16, file 2015–04–08_10–16–03_EDT, at 1 (saying that Agent 1 knew about their relationship); GE–17, at 6–7 (identifying Agent 1 before the first undercover appointment); GE–21, at 5–6 (identifying Agent 1 before the second undercover appointment); *see* GE–21, at 8 (asking the Respondent to bring Agent 1's prescriptions to his rendezvous with CI at Walmart to save her money); *see also* GE–28, file 2015–04–22_13–03–23_EDT, at 4–5 (recognizing Agent 1 as CI's friend before the third and fourth undercover appointments); GE–28, file 2015–04–28_20–23–38_EDT, at 1 (identifying Agent 1 and Agent 2 as CI's friends before the third and fourth undercover appointments); GE–40, at 2 (recognizing that, at the time of Agent 2's appointment, the Respondent knew that Agent 2 was affiliated with CI and Agent 1).

[61] GE–16, file 2015–03–18_11–03–33_EDT, at 2–4 (suggesting that CI could send a friend in to get prescriptions before the first undercover appointment); GE–17, at 3 (same, and acknowledging, before the first undercover appointment, that any prescriptions to CI's friends would be diverted to CI); GE–17, at 7 (advising that the prescriptions he gave to Agent 1 would be fine for CI to take); GE–18, at 3 (stating, before the first undercover appointment, that the Respondent would write prescriptions for Agent 1 so CI could have the medication); *see* GE–14, at 1 (identifying Agent 1 as CI's friend, and discussing how the Respondent "hooked [CI] up," before the second undercover appointment); GE–16, file 2015–04–02_14–15–50_EDT, at 1–2 (same); GE–21, at 13 (thanking the Respondent for "hooking" her up before the second undercover appointment); GE–28, file 2015–04–28_20–23–38_EDT, at 1 (asking the Respondent to "[h]ook" up CI's friend before the third and fourth undercover appointments).

[62] *E.g.,* GE–16, file 2015–04–02_14–15–50_EDT, at 2; GE–16, file 2015–04–02_15–04–43_EDT, at 1–2.

[63] GE–28, file 2015–04–27_14–45–16_EDT, at 1.

[64] GE–18, at 3 (discussing the first undercover appointment); GE–23 (discussing, before the second undercover appointment, the need to space out the appointments more); *see* GE–16, file 2015–04–06_20–59–35_EDT, at 2 (discussing the second undercover appointment); *see also* GE–28, file 2015–04–22_10–28–41_EDT, at 3–4 (discussing the third and fourth undercover appointments); GE–28, file 2015–04–22_13–03–23_EDT, at 4 (same); GE–28, file 2015–04–28_20–23–38_EDT, at 1 (same); GE–29, at 7 (same).

[65] GE–18, at 3 (instructing CI to tell Agent 1 to "play it straight" and tell him what he needed to write in his chart at the first undercover appointment).

[66] GE–14, at 1 (telling CI, after the first undercover appointment, that he was happy to meet Agent 1 and hoped it helped, and receiving thanks from CI for "hooking" her up); GE–14, at 2 (acknowledging that the prescriptions that he gave to Agent 1 went to CI); GE–19, at 1 (asking CI if everything "went smooth with getting your medication" and expressing that he was happy to help); GE–40, at 1–2 (asking CI if she got the medication and expressing that he was "glad all that worked out").

Moreover, the fact that a registrant conducted a medical appointment before prescribing controlled substances does not, standing by itself, validate the prescriptions issued; rather, an appointment may be used by a prescriber as ''a sham justification to support an unlawful prescription.'' *McNichol,* 77 Fed. Reg. at 57148. An appointment can constitute a perfunctory, sham examination if the registrant ''already agreed to issue'' certain prescriptions to a patient. *Darryl J. Mohr, M.D.,* 77 Fed. Reg. 34998, 35000 (2012).

This is precisely what happened here. Before each of the first four undercover appointments, the record unambiguously shows that the Respondent knew exactly what he would prescribe to Agents 1 and 2 before they ever walked through his door, because he knew what drugs CI had requested. For example, the Respondent prescribed Hycodan to Agent 1, even though she was not coughing during her appointment, because he had told CI that he would get eight ounces of cough syrup to her. GE–33, at 1; GE–38, at 3–4, 8; Tr. 113. Following the second appointment, the Respondent himself acknowledged the sham nature of the appointment; he stated that he had made small talk with Agent 1 because ''we had to be in there more than ten seconds'' so that his ''nosy nurse'' would not think, ''[d]ang, why is this appointment over with in ten seconds?'' GE–27, at 1, 5. It is not surprising that, during Agent 1's second appointment, the Respondent did not bother to conduct even a sham physical examination. *See* GE–24–25; Tr. 103–04, 132.

The facts of this case present an appalling and flagrant disregard of a registrant's duty to prescribe controlled substances only to legitimate patients. While the Respondent told CI that his feelings for her needed to be ''totally separate from [his] medical practice,'' GE–20, he was unable to follow his own internal guidance. In fact, the size of the Respondent's diversion was significant: during the first four undercover appointments, the Respondent prescribed a total of 160 units of Norco and eight ounces of Hycodan to the undercover agents, who he believed would divert those drugs to CI.[67] The Respondent repeatedly joked about providing CI access to all the drugs that she wanted.[68] Even though the Respondent did not take his responsibilities as a registrant seriously, he did understand the potential legal consequences of his actions. The Respondent repeatedly expressed a fear of getting in trouble for diverting drugs to CI.[69] This reflects that the Respondent undoubtedly knew that his actions were wrong.[70]

I find that, during the first four undercover appointments, the Respondent knew that Agent 1 and Agent 2 were not real patients and that at least some of the medications he prescribed to them would be given to CI. I find that the Respondent prescribed medications to Agent 1 and Agent 2 upon CI's request for those medications. I further find that, when the Respondent wrote prescriptions to Agent 1 and Agent 2 during those four appointments, the Respondent intended to divert drugs to CI. Thus, by ''providing evidence showing that [the Respondent] knowingly diverted drugs,'' the Government proved that the Respondent acted outside of the usual course of his professional practice and lacked a legitimate medical purpose. *See Danton,* 76 Fed. Reg. at 60901. Therefore, the Government's allegations that the first four undercover appointments violated 21 U.S.C. §§ 841(a) and 842(a), and 21 CFR § 1306.04(a) are **SUSTAINED** by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

To the extent that the Respondent's actions are interpreted as prescribing controlled substances to CI indirectly,[71] his prescriptions are grave violations of 21 CFR 1306.04(a). On this point, this case bears a striking similarity to *Annicol Marrocco, M.D.,* 80 FR 28695 (2015). In that case, Dr. Marrocco prescribed controlled substances to her lover, but did not physically see her lover for three to six months while he was using those prescriptions. *Id.* at 28703. The DEA found that Dr. Marrocco lacked a legitimate purpose for her prescriptions because she was unable to supervise her lover's use of his medication, which reflected ''a stunning disregard for [Dr. Marrocco's] obligations as a prescriber of controlled substances.'' *Id.; see Figueroa,* 73 FR at 40381 (noting that failure to see a patient before prescribing medication deviates from the legitimate practice of medicine). Similarly, other than two brief interactions in public places, the Respondent never saw CI while he was prescribing controlled substances to Agent 1 and Agent 2 to divert to CI. Therefore, the Respondent could not monitor CI's use of controlled substances.

Additionally, prescribing controlled substances based on a patient's request, ''rather than the result of the application of the physician's medical judgment,'' lacks a legitimate medical purpose. *Golden,* 61 FR at 24812 (citing *Dougherty,* 60 FR 55047; *Borcherding,* 60 FR 28796). The Respondent's prescriptions to Agent 1 and Agent 2 were based only on CI's request for certain controlled substances, not on any physical examination or medical evaluation. Under Mississippi Administrative Rule 1.4(a), such prescribing establishes that the Respondent lacked good faith in issuing these prescriptions.

For these reasons, to the extent that the Respondent's 2015 prescriptions to Agent 1 and Agent 2 are perceived as indirect prescriptions to CI, they clearly violate Mississippi Administrative Rules 1.4 and 1.16, Mississippi Code §§ 73–25–29(3) and (13), and 21 CFR 1306.04(a), and the Government's allegations to that effect are

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[67] GE–11, at 1 (prescribing 40 units of Norco 10/325 to Agent 1 at the first undercover appointment); GE–26, at 1 (prescribing 40 units of Norco 10/325 to Agent 1 at the second undercover appointment); GE–32 (prescribing 40 units of Norco 10/325 to Agent 1 at the third undercover appointment); GE–33, at 1 (prescribing eight ounces of Hycodan to Agent 1 at the third undercover appointment); GE–36, at 1 (prescribing 40 units of Norco 10/325 to Agent 2 at the fourth undercover appointment).

[68] GE–16, file 2015–03–17_13–07–36_EDT, at 7 (joking before the first undercover appointment); GE–16, file 2015–03–18_11–03–33_EDT, at 4 (same); GE–16, file 2015–04–02_15–04–43_EDT, at 1–2 (joking before the second undercover appointment); GE–29, at 9 (joking after the third and fourth undercover appointments); GE–38, at 2 (joking before the third and fourth undercover appointments).

[69] GE–16, file 2015–03–17_13–07–36_EDT, at 7 (admitting fear before the first undercover appointment); GE–16, file 2015–04–02_14–15–50_EDT, at 2 (instructing CI to keep things hidden); GE–17, at 2 (expressing fear before the first undercover appointment); *see* GE–14, at 1 (expressing fear after the first undercover appointment); GE–16, file 2015–04–02_15–04–43_EDT, at 2 (discussing avoiding detection before the second undercover appointment); GE–16, file 2015–04–07_13–29–34_EDT, at 2 (same); GE–16, file 2015–04–07_18–28–45_EDT, at 7–8 (same); *see also* GE–28, file 2015–04–22_10–28–41_EDT, at 3–4 (expressing concern about getting caught before the third and fourth undercover appointments); GE–28, file 2015–04–22_13–03–23_EDT, at 4 (same); GE–38, at 2 (same).

[70] *See* GE–16, file 2015–03–18_11–03–33_EDT, at 2–3 (reflecting his knowledge that his actions were wrongful before the first undercover appointment); GE–38, at 8 (expressing his fear that he might be ''busted'' by the ''drug police'').

[71] *See supra* note 43.

SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

In addition, the Respondent diverted controlled substances to CI through the undercover agents after he knew that CI attempted to commit suicide. Such actions reflect an astonishing level of irresponsibility in the Respondent's prescribing activity. In *McNichol,* the DEA held under Factors Two and Four that a prescriber's statement, which reflected concern about putting a patient potentially "in jeopardy of overdose," made it "clear that [the prescriber] believed that [the patient] was a drug abuser." 77 FR at 57149. Similarly, in *Jayam Krishna-Iyer,* the DEA held that "[a] practitioner who ignores the warning signs that [his] patients are either personally abusing or diverting controlled substances commits 'acts inconsistent with the public interest,' 21 U.S.C. 824(a)(4), even if [he] is merely gullible or naïve." 74 FR at 460 n.3. Additionally, it is "relevant that [a registrant], knowing that the CI had been treated for drug abuse, facilitated her access to controlled substances." *Golden,* 61 FR at 24812.

Here, the facts indicate that the Respondent knew his prescribing actions put CI's health in danger. The Respondent knew that CI previously had attempted to commit suicide using drugs he prescribed to her. He knew she was still depressed. GE–28, file 2015–04–15_21–30–59_EDT, at 9. He expressed fear and concern that she would take too many pills, resulting in "unfixably bad" damage and a "long, agonizing, painful way to go." GE–14, at 1; GE–17, at 4. In spite of all of this, the Respondent continued to divert controlled substances to CI and said he was "glad" to do so. GE–19, at 1; GE–40, at 1; Tr. 230–31. Under these circumstances, the Respondent's continued prescribing controlled of substances to CI reflects negatively on the Respondent's experience in dispensing controlled substances.

B. Undercover Appointment #5

Although the Government did not allege that the Respondent's prescriptions to Agent 1 during the fifth undercover appointment were knowing attempts to divert drugs to CI, the Government alleged that the October 2015 prescriptions violated 21 U.S.C. 841(a) and 842(a) and 21 CFR 1306.04(a) because the Respondent knew or should have known that Agent 1's prescription requests were fraudulent. *See* ALJ–1, at 3–4.

The Government presented no evidence of any communications between the Respondent and CI or Agent 1 immediately preceding Agent 1's October 2015 appointment. At the appointment, Agent 1 met with the Respondent, who examined her ears, nose, and throat. Tr. 120, 132. The Respondent appeared to not remember Agent 1. Tr. 120, 135, 452; *see* GE–42–43.

Only the first portion of the appointment was recorded, and no witnesses were able to confidently recall the whole conversation between Agent 1 and the Respondent. In response to Agent 1's inquiry, the Respondent indicated during the appointment that he did not remember Agent 2. GE–42–43. When Agent 1 asked the Respondent if he had heard from CI lately, the Respondent paused, and looked surprised, before saying that he had not. Tr. 122–23, 135, 452–53. Agent 1 said that she needed the "same as before," but did not tell the Respondent that she had any specific complaints. GE–42–43; Tr. 454. The Respondent discussed the efficacy of medication with Agent 1. GE–43, at 2–3. Agent 1 never said she had a cough. GE–42–43; Tr. 126, 454. Nonetheless, the Respondent prescribed cough syrup, among other things, to Agent 1. GE–45; Tr. 139.

The Respondent's medical file for Agent 1 indicated that Agent 1 had "migraine headaches, as before Weather changes may make it worse Maxalt helps most of the time Norco works okay as a backup Dry [illegible] cough; no [illegible] to be allergy related Allergy symptoms Ears clear OC/OP clear Nose c̄ somewhat [illegible] Lungs clear." GE–60, at 4. The Respondent also recorded that he wrote five prescriptions to CI, including 30 units of Norco 5/325 and four ounces of Hycodan. GE–60, at 4.

These facts summarize the totality of the evidence before me concerning the October 2015 undercover appointment. Based on these facts, I find that there is not substantial evidence that the Respondent knew or should have known that Agent 1's prescription requests were fraudulent. The recordings and testimony do not clearly indicate that Agent 1 was presenting sham symptoms to the Respondent. Agent 1's patient file indicated that the Respondent examined Agent 1, recorded her complaints, and recorded the prescriptions he gave to her. Importantly, the Government did *not* allege that the Respondent's medical record for Agent 1 from the October appointment was deficient; it only alleged that he *knew or should have known* that Agent 1's prescription requests were fraudulent. The Government bears the burden of proof on this point. "[U]nder the substantial evidence test, the evidence must 'do more than create a suspicion of the existence of the fact to be established.'" *Alvin Darby, M.D.,* 75 FR 26993, 26999 n.31 (2010) (citing *NLRB* v. *Columbian Enameling & Stamping Co.,* 306 U.S. 292, 300 (1939)). The Government failed to meet this burden. The Government offered insufficient evidence to support a conclusion that the Respondent knew or should have known that, five and a half months after last seeing Agent 1, and while reviewing a new medical chart, her requests during the October 2015 appointment were fraudulent. Therefore, the Government's allegations that the fifth undercover appointment violated 21 U.S.C. 841(a) and 842(a), and 21 CFR 1306.04(a), because the Respondent knew or should have known that Agent 1's prescription requests were fraudulent are NOT SUSTAINED.

Allegation 5: Prescriptions Issued in 2014 and 2015

The Government alleged that, from February 2014 to October 2015, the Respondent unlawfully prescribed controlled substances in violation of 21 U.S.C. 841(a) and 842(a). ALJ–1, at 2. Specifically, the Government alleged that the Respondent prescribed controlled substances when he knew or should have known that they were not prescribed for legitimate medical purposes, and were not written in the usual course of professional practice, in violation of 21 CFR 1306.04(a) and Mississippi Code §§ 41–29–137(a)(1) and 41–29–141(1). ALJ–1, at 2. Those sections of the Mississippi Code provide that it is illegal for practitioners to dispense Schedule II controlled substances without a valid written prescription. Miss. Code §§ 41–29–137(a)(1), 41–29–141(1).

Under Allegation 1, I sustained the Government's allegations that the Respondent's 2014 prescriptions to CI on May 22, June 17, September 11, October 6, and December 4 were outside the usual course of his professional practice and were illegitimate prescriptions that violated 21 CFR 1306.04(a). Under Allegation 2, I sustained the Government's allegations that the Respondent's 2014 prescriptions to CI on April 9, May 19, July 24, and September 8 were outside the usual course of his professional practice and were illegitimate prescriptions that violated 21 CFR 1306.04(a). Under Allegation 3, I sustained the Government's allegations that the Respondent's 2014 prescriptions to Kid 2 on February 7, July 23, September 2, and November 3, and the Respondent's prescriptions to

Kid 1 on June 17 and November 19, were outside the usual course of his professional practice and were illegitimate prescriptions that violated 21 CFR 1306.04(a). Finally, under Allegation 4, I sustained the Government's allegations that the Respondent's prescriptions written during the first four undercover appointments in 2015 were fraudulent and violated 21 CFR 1306.04(a).

I have held that all of these prescriptions were issued outside of the Respondent's usual course of professional practice and were not issued for legitimate medical purposes. Therefore, the Government's allegation that the Respondent violated 21 CFR 1306.04(a) is SUSTAINED by a preponderance of the evidence, and weighs in favor of the revocation sought by the Government. The Government also established that some prescriptions were invalid because CI, rather than the named patient, was the actual intended recipient of several prescriptions. The Government's allegations that the Respondent's six prescriptions to CI's children, identified *supra,* and 2015 hydrocodone combination product prescriptions to the undercover agents at the first four undercover appointments violated Mississippi Code §§ 41–29–137(a)(1) and 41–29–141(1) are SUSTAINED.[72] Because the Respondent issued illegitimate prescriptions, the Government's allegations that the Respondent violated 21 U.S.C. 841(a) and 842(a) are SUSTAINED by a preponderance of the evidence, and weigh in favor of the revocation sought by the Government.

Allegation 6: Meperidine Used in Suicide Attempt

The Government alleged that the Respondent prescribed 30 dosage units of meperidine 50 mg to CI, which she used to try to kill herself. ALJ–1, at 3. The evidence shows that the Respondent prescribed Demerol to CI on September 2, 2014. GE–2, at 12; GE–49, at 2; Tr. 222, 296–97, 317–18, 382. The Respondent appears to have been the only person to prescribe Demerol to CI. *See* GE–49. CI used the Demerol to attempt to commit suicide in December 2014. Tr. 222, 315–17. The Government, however, did not specify or argue why this Demerol prescription was improper. The Government did not allege or argue that the Respondent failed to conduct a physical examination of CI, or failed to maintain proper medical charts, when he prescribed Demerol to CI. The Government did not allege or argue that the Respondent knew or anticipated that CI would attempt to commit suicide using the Demerol he prescribed to her. The Government did not even allege or argue that the Respondent possessed anything other than a legitimate intent to treat CI's physical symptoms when he prescribed Demerol to her. Therefore, to the extent that the Government alleged that the Respondent's Demerol prescription to CI merits revocation of his COR, the Government's allegation is NOT SUSTAINED.

Under Factors Two and Four,[73] the Respondent's prescribing conduct indicates that his continued registration is not in the public interest. Therefore, Factors Two and Four militate strongly in favor of revocation of the Respondent's COR.

RECOMMENDATION

Even if the Respondent had knowingly attempted to divert controlled substances to CI only one time, that alone would have been sufficient to make a *prima facie* case for revocation of the Respondent's license. *See MacKay* v. *DEA,* 664 F.3d 808, 819 (10th Cir. 2011). "[P]roof of a single act of intentional or knowing diversion is sufficient to satisfy the Government's *prima facie* burden of showing that a practitioner's continued registration is inconsistent with the public interest, and if unrebutted by a showing that the practitioner accepts responsibility for his misconduct and will not engage in future misconduct, warrants the revocation of a registration." *McNichol,* 77 FR at 57145 (internal citations omitted); *see also Krishna-Iyer,* 74 FR at 462–64; *Alan H. Olefsky,* 57 FR 928, 928–29 (1992). In cases of knowing diversion, "the [DEA] has an interest in deterring [the Respondent] and others from engaging in similar egregious behavior." *Michael A. White, M.D.,* 79 FR 62957, 62967 (2014).

Here, the Government has proven far more than one act of knowing diversion. The Government has proven that the Respondent repeatedly and continually issued illegitimate prescriptions to CI and others for multiple types of drugs based solely on CI's request. The Government has proven that, on multiple occasions, the Respondent knowingly issued fraudulent prescriptions with the intent to divert drugs to CI. The Respondent's improper prescribing constituted an egregious level of intentional diversion. Accordingly, Factors Two and Four weigh heavily against the Respondent, and the Government has established a *prima facie* case supporting revocation of the Respondent's registration. Further, after evaluating all of the above established facts, I find that considerations of both specific and general deterrence also weigh in favor of revocation in this case.

Because the Government has made a *prima facie* case that the Respondent's continued registration would be inconsistent with the public interest, the Respondent had the burden of production to "present[] sufficient mitigating evidence" to show why he can be entrusted with a registration. *See Med. Shoppe—Jonesborough,* 73 FR at 387 (quoting *Samuel S. Jackson, D.D.S.,* 72 FR 23848, 23853 (2007)). Specifically, to rebut the Government's *prima facie* case, the Respondent must have both accepted responsibility for his actions and demonstrated that he would not engage in future misconduct. *Stodola,* 74 FR at 20734–35. However, the Respondent offered no evidence[74] that he accepted responsibility for his misconduct or reformed his ways. Therefore, the Respondent failed to rebut the Government's *prima facie* case.

Because the Government proved that the Respondent's registration is inconsistent with the public interest, and because the Respondent failed to rebut the Government's *prima facie* case, I RECOMMEND that the Respondent's DEA Certificate of Registration be REVOKED and any applications for renewal or modification of his license be DENIED.

Dated: June 1, 2016

s/Charles Wm. Dorman

Administrative Law Judge

[FR Doc. 2016–19595 Filed 8–16–16; 8:45 am]

BILLING CODE 4410–09–P

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[72] Hydrocodone combination products were reclassified by the federal government as Schedule II controlled substances as of October 6, 2014. Stip. 6. The Government has not shown how hydrocodone combination products are scheduled in the state of Mississippi. The Government's allegations that the Respondent's prescriptions predating October 6, 2014, violated Mississippi Code §§ 41–29–137(a)(1) and 41–29–141(1), which only address Schedule II controlled substances, are NOT SUSTAINED.

[73] Both parties specifically discussed Factor Five in their post-hearing briefs. Factor Five considers conduct not otherwise addressed under Factors One through Four. 21 U.S.C. 823(f)(5). As discussed *supra,* the Respondent's actions in this case are most appropriately analyzed under Factors Two and Four. Therefore, consideration of this conduct under Factor Five, the "catch-all" factor, is inappropriate.

[74] The Government requested that I draw an adverse inference against the Respondent because of his failure to testify at the hearing. ALJ–35, at 27–28. However, I decline to do so because an adverse inference is unnecessary in light of the overwhelming evidence against the Respondent.

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket No. DEA–392]

Bulk Manufacturer of Controlled Substances Application: Stepan Company

ACTION: Notice of application.

DATES: Registered bulk manufacturers of the affected basic classes, and applicants therefore, may file written comments on or objections to the issuance of the proposed registration in accordance with 21 CFR 1301.33(a) on or before October 17, 2016.

ADDRESSES: Written comments should be sent to: Drug Enforcement Administration, Attention: DEA Federal Register Representative/ODW, 8701 Morrissette Drive, Springfield, Virginia 22152.

SUPPLEMENTARY INFORMATION: The Attorney General has delegated her authority under the Controlled Substances Act to the Administrator of the Drug Enforcement Administration (DEA), 28 CFR 0.100(b). Authority to exercise all necessary functions with respect to the promulgation and implementation of 21 CFR part 1301, incident to the registration of manufacturers, distributors, dispensers, importers, and exporters of controlled substances (other than final orders in connection with suspension, denial, or revocation of registration) has been redelegated to the Deputy Assistant Administrator of the DEA Office of Diversion Control (“Deputy Assistant Administrator”) pursuant to section 7 of 28 CFR part 0, appendix to subpart R.

In accordance with 21 CFR 1301.33(a), this is notice that on April 21, 2016, Stepan Company, Natural Products Dept., 100 W. Hunter Avenue, Maywood, New Jersey 07607 applied to be registered as a bulk manufacturer of the following basic classes of controlled substances:

Controlled substance	Schedule
Cocaine (9041)	II
Ecgonine (9180)	II

The company plans to manufacture the listed controlled substances in bulk for distribution to its customers.

Dated: August 10, 2016.

Louis J. Milione,

Deputy Assistant Administrator.

[FR Doc. 2016–19592 Filed 8–16–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF JUSTICE

[Docket No. ODAG 164]

Notice of Federal Advisory Committee Meeting

AGENCY: Department of Justice.

ACTION: Notice of Federal Advisory Committee meeting. Request for public comment.

SUMMARY: The National Commission on Forensic Science will hold meeting eleven at the time and location listed below.

DATES:

(1) *Public Hearing.* The meeting will be held on September 12, 2016 from 12:30 p.m. to 5:15 p.m. and September 13, 2016 from 8:00 a.m. to 4:00 p.m.

(2) *Written Public Comment.* Written public comment regarding National Commission on Forensic Science meeting materials can be submitted through *www.regulations.gov* starting on August 29, 2016. Any comments should be posted to *www.regulations.gov* no later than September 28, 2016.

ADDRESSES: Location: National Institute of Standards and Technology (NIST), Administrative Building #101, West Square Conference Room, 100 Bureau Drive, Gaithersburg, MD 20899. Please note admittance instructions under the **SUPPLEMENTARY INFORMATION** section of this notice.

FOR FURTHER INFORMATION CONTACT: Jonathan McGrath, Ph.D., Senior Policy Analyst at the National Institute of Justice and Designated Federal Official, 810 7th Street NW., Washington, DC 20531, by email at *Jonathan.McGrath@usdoj.gov* by phone at (202) 514–6277.

SUPPLEMENTARY INFORMATION: *Agenda:* Open Meeting: The Commission will meet on September 12, 2016, 12:30 p.m. to 5:15 p.m. and September 13, 2016, 8:00 a.m. to 4:00 p.m. On September 12, the Commission will receive a briefing on technical merit review and Subcommittee status reports. On September 13, the Commission will receive Subcommittee status reports, a briefing on statistical statements of relevance, an update on the Forensic Science Discipline Review from DOJ's Office of Legal Policy and a discussion of ethics issues for NCFS members from DOJ's Departmental Ethics Office. Note: agenda items, including designation of presentation dates are subject to change. A final agenda will be posted to the Commission's Web site in advance of the meeting.

Meeting Accessibility: Pursuant to 41 CFR 102–3.140 through 102–3.165 and the availability of space, the meeting scheduled for September 12, 2016, 12:30 p.m. to 5:15 p.m. and September 13, 2016, 8:00 a.m. to 4:00 p.m. at NIST is open to the public and webcast.

New Visitor Access Requirement: For participants attending in person, please note that federal agencies, including NIST, can only accept a state-issued driver's license or identification card for access to federal facilities if such license or identification card is issued by a state that is compliant with the REAL ID Act of 2005 (Pub. L. 109–13), or by a state that has an extension for REAL ID compliance. NIST currently accepts other forms of federal-issued identification in lieu of a state-issued driver's license. Driver's licenses from six states and territories are not compliant and will not be accepted as identification: Minnesota, Illinois, Missouri, Washington, and American Samoa. In addition, NIST will accept only enhanced driver's licenses (identified by the American Flag on the face of the card) from two states: Minnesota and Washington State. For a list of alternative identification, please visit: *http://www.nist.gov/public_affairs/visitor/.*

Non U.S. Citizens Please Note: All foreign national visitors who do not have permanent resident status and who wish to register for the above meeting must supply additional information. Failure to provide this information prior to arrival will result, at a minimum, in significant delays (up to 24 hours) in entering the facility. Authority to gather this information is derived from United States Department of Commerce Department Administrative Order (DAO) number 207–12. When on-line registration is open, the required NIST–1260 form will be available. The NIST–1260 form needs to be submitted at least 5 business days in advance of the meeting.

Written Comments: Pursuant to section 10(a)(3) of the FACA and 41 CFR 102–3.105(j) and 102–3.140, the public or interested organizations may submit written comments to the Commission in response to the stated agenda and meeting material. Meeting material, including work products will be made available on the Commission's Web site: *http://www.justice.gov/ncfs.*

Oral Comments: In addition to written statements, members of the public may present oral comments at 5:00 p.m. on September 12, 2016 and at 3:45 p.m. on September 13, 2016. Those individuals interested in making oral comments should indicate their intent through the on-line registration form and time will be allocated on a first-come, first-served basis. Time allotted for an individual's comment period will be limited to no more than 3 minutes. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled public comment periods, written comments can be submitted through *www.regulations.gov* in lieu of oral comments.

Registration: Individuals and entities who wish to attend the public meeting are required to pre-register for the meeting on-line by clicking the registration link found at: *https://www.justice.gov/ncfs/term-2-meetings-8-15#s10.* Anyone wishing to attend this meeting must register by 5:00 p.m. (EST), Tuesday, September 6, 2016. Registered attendees will receive security and campus instructions prior to the workshop. On-site registration will not be available for this meeting, however, the meeting will be webcast.

Additional Information: The Department of Justice welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs, in coordination with National Institute of Standards and Technology. If you require special accommodations, please indicate your requirements on the online registration form. Please note that seating is limited for public attendees, and will be granted on a first come first serve basis. An overflow room may be used if main conference room spaces is exceeded.

Dated: August 11, 2016.

Andrew J. Bruck,

Acting Chief of Staff and Senior Counsel to the Deputy Attorney General, National Commission on Forensic Science.

[FR Doc. 2016–19628 Filed 8–16–16; 8:45 am]

BILLING CODE 4410–18–P

DEPARTMENT OF LABOR

Employment and Training Administration

Notice of a Public Meeting of the Advisory Committee on Apprenticeship (ACA)

AGENCY: Employment and Training Administration (ETA), Labor.

ACTION: Notice of a public meeting.

SUMMARY: Pursuant to Section 10 of the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2 § 10), notice is hereby given to announce an open meeting of the Advisory Committee on Apprenticeship (ACA) on Tuesday, September 27, 2016 and Wednesday, September 28, 2016. The ACA is a discretionary committee established by the Secretary of Labor, in accordance with FACA, as amended in 5 U.S.C. App. 2, and its implementing regulations (41 CFR 101–6 and 102–3). All meetings of the ACA are open to the public.

DATES: The meeting will begin at approximately 11:00 a.m. Eastern Standard Time on Tuesday, September 27, 2016, at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW., Washington, DC 20210, and will continue until approximately 4:30 p.m. The meeting will reconvene on Wednesday, September 28, 2016, at approximately 8:30 a.m. Eastern Standard Time at the U.S. Department of Labor, Frances Perkins Building, 200 Constitution Avenue NW., Washington, DC 20210 and adjourn at approximately 12:00 p.m. Any updates to the agenda and meeting logistics will be posted on the Office of Apprenticeship's homepage: *http://www.dol.gov/apprenticeship.*

FOR FURTHER INFORMATION CONTACT: The Designated Federal Official, Mr. John V. Ladd, Administrator, Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Room C–5321, Washington, DC 20210, Telephone: (202) 693–2796 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: In order to promote openness, and increase public participation, webinar and audio conference technology will be used throughout the meeting. Webinar and audio instructions will be posted prominently on the Office of Apprenticeship homepage: *http://www.dol.gov/apprenticeship.* Members of the public can attend the meeting in-person or virtually. Members of the public that will attend the meeting in-person are encouraged to arrive early to allow for security clearance into the Frances Perkins Building.

Security and Transportation Instructions for the Frances Perkins Building

Meeting participants should use the visitor's entrance to access the Frances Perkins Building, one block north of Constitution Avenue on 3rd and C Streets NW. For security purposes meeting participants must:

1. Present valid photo identification (ID) to receive a visitor badge.
2. Know the name of the event you are attending: The meeting event is the Advisory Committee on Apprenticeship meeting.
3. Visitor badges are issued by the security officer at the Visitor Entrance located at 3rd and C Streets NW., as described above.
4. Laptops and other electronic devices may be inspected and logged for identification purposes.
5. Due to limited parking options, Metro rail is the easiest way to travel to the Frances Perkins Building. For individuals wishing to take metro rail, the closest metro stop to the building is Judiciary Square on the Red Line.

Notice of Intent to Attend the Meeting: All meeting participants are being asked to submit a notice of intent to attend by Tuesday, September 20, 2016, via email to Mr. John V. Ladd at: *oa.administrator@dol.gov,* with the subject line "September 2016 ACA Meeting."

1. If individuals have special needs and/or disabilities that will require special accommodations, please contact Kenya Huckaby on (202) 693–3795 or via email at *huckaby.kenya@dol.gov* no later than Tuesday, September 20, 2016.
2. Any member of the public who wishes to file written data or comments pertaining to the agenda may do so by sending the data or comments to Mr. John V. Ladd via email at *oa.administrator@dol.gov,* subject line "September 2016 ACA Meeting," or to the Office of Apprenticeship, Employment and Training Administration, U.S. Department of Labor, Room C–5321, 200 Constitution Avenue NW., Washington, DC 20210. Such submissions will be included in the record for the meeting if received by Tuesday, September 20, 2016.
3. See below regarding members of the public wishing to speak at the ACA meeting.

Purpose of the Meeting and Topics To Be Discussed

The purpose of the September meeting is to orient the newly appointed members, continue to focus on apprenticeship expansion and growth, diversity and increasing opportunities, how best to increase Registered Apprenticeship utilization, as well as priorities for the new ACA term.

The agenda will cover the following topics:

- Expanding Registered Apprenticeship Opportunities for Women and Youth
- Ongoing Industry Engagement
- ApprenticeshipUSA and LEADERS
- New Member Orientation
- National Apprenticeship Week
- Building Innovative Apprenticeship Models
- Presentation by the Urban Institute
- Other Matters of Interest to the Apprenticeship Community
- Public Comment
- Adjourn

The agenda and meeting logistics may be updated should priority items come before the ACA between the time of this publication and the scheduled date of the ACA meeting. All meeting updates will be posted to the Office of Apprenticeship's homepage: *http://www.dol.gov/apprenticeship.* Any member of the public who wishes to speak at the meeting should indicate the nature of the intended presentation and the amount of time needed by furnishing a written statement to the Designated Federal Official, Mr. John V. Ladd, by Tuesday, September 20, 2016. The Chairperson will announce at the beginning of the meeting the extent to which time will permit the granting of such requests.

Portia Wu,

Assistant Secretary for the Employment and Training Administration.

[FR Doc. 2016–19615 Filed 8–16–16; 8:45 am]

BILLING CODE 4510–FR–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Prohibited Transaction Class Exemption for Certain Transactions Between Investment Companies and Employee Benefit Plans (PTE 1977–4)

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Employee Benefits Security Administration (EBSA) sponsored information collection request (ICR) titled, "Prohibited Transaction Class Exemption for Certain Transactions Between Investment Companies and Employee Benefit Plans (PTE 1977–4)," to the Office of Management and Budget (OMB) for review and approval for continued use, without change, in accordance with the Paperwork Reduction Act of 1995 (PRA), 44 U.S.C. 3501 *et seq.* Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 16, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the *RegInfo.gov* Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201607-1210-005* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–EBSA, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor—OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or by email at *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks to extend PRA authority for the information collection requirements contained in the Prohibited Transaction Class Exemption for Certain Transactions Between Investment Companies and Employee Benefit Plans (PTE 1977–4). Under circumstances the Employee Retirement Income Security Act (ERISA) would otherwise prohibit, PTE 1977–4 permits an employee benefit plan to purchase and sell shares of an open-end investment company (mutual fund) when a fiduciary with respect to the plan is also the investment advisor for the mutual fund. PTE 1977–4 incorporates three basic disclosure requirements. The first requirement is to disclose any redemption fees in the current prospectus of the open-end mutual fund. The second requirement is that, at the time of the purchase or sale of such mutual fund shares, an independent fiduciary receive a copy of the current prospectus issued by the open-end mutual fund and full written disclosure of the investment advisory fees charged to or paid by the plan and the open-end mutual fund to the investment advisor. The third requirement is that the independent fiduciary (1) be notified of any changes in the fees and (2) give written approval for the plan to purchase or sell affected mutual fund shares or the plan to continue possession of any such mutual fund shares acquired before the fee changes. ERISA section 408(a) and Internal Revenue Code section 4975(c)(2) authorize this information collection. *See* 29 U.S.C. 1108(a); 26 U.S.C. 4975(c)(2).

A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1210–0049.

OMB authorization for an ICR cannot be for more than three (3) years without renewal, and the current approval for this collection is scheduled to expire on August 31, 2016. The DOL seeks to extend PRA authorization for this information collection for three (3) more years, without any change to existing requirements. The DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on May 26, 2016 (81 FR 33550).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1210–0049. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other

technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–EBSA.

Title of Collection: Prohibited Transaction Class Exemption for Certain Transactions Between Investment Companies and Employee Benefit Plans (PTE 1977–4).

OMB Control Number: 1210–0049.

Affected Public: Private Sector—businesses or other for-profits and not-for-profit institutions.

Total Estimated Number of Respondents: 873.

Total Estimated Number of Responses: 271,238.

Total Estimated Annual Time Burden: 23,040 hours.

Total Estimated Annual Other Costs Burden: $117,069.

Dated: August 11, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–19613 Filed 8–16–16; 8:45 am]

BILLING CODE 4510–29–P

DEPARTMENT OF LABOR

Office of the Secretary

Agency Information Collection Activities; Submission for OMB Review; Comment Request; Death Gratuity

ACTION: Notice.

SUMMARY: The Department of Labor (DOL) is submitting the Office of Workers' Compensation Programs (OWCP) sponsored information collection request (ICR) revision titled, "Death Gratuity," to the Office of Management and Budget (OMB) for review and approval for use in accordance with the Paperwork Reduction Act (PRA) of 1995 (44 U.S.C. 3501 *et seq.*). Public comments on the ICR are invited.

DATES: The OMB will consider all written comments that agency receives on or before September 16, 2016.

ADDRESSES: A copy of this ICR with applicable supporting documentation; including a description of the likely respondents, proposed frequency of response, and estimated total burden may be obtained free of charge from the RegInfo.gov Web site at *http://www.reginfo.gov/public/do/PRAViewICR?ref_nbr=201603–1240–001* (this link will only become active on the day following publication of this notice) or by contacting Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Submit comments about this request by mail or courier to the Office of Information and Regulatory Affairs, Attn: OMB Desk Officer for DOL–OWCP, Office of Management and Budget, Room 10235, 725 17th Street NW., Washington, DC 20503; by Fax: 202–395–5806 (this is not a toll-free number); or by email: *OIRA_submission@omb.eop.gov.* Commenters are encouraged, but not required, to send a courtesy copy of any comments by mail or courier to the U.S. Department of Labor-OASAM, Office of the Chief Information Officer, Attn: Departmental Information Compliance Management Program, Room N1301, 200 Constitution Avenue NW., Washington, DC 20210; or by email: *DOL_PRA_PUBLIC@dol.gov.*

FOR FURTHER INFORMATION CONTACT: Michel Smyth by telephone at 202–693–4129, TTY 202–693–8064, (these are not toll-free numbers) or sending an email to *DOL_PRA_PUBLIC@dol.gov.*

Authority: 44 U.S.C. 3507(a)(1)(D).

SUPPLEMENTARY INFORMATION: This ICR seeks approval under the PRA for revisions to the Death Gratuity Forms. The National Defense Authorization Act for Fiscal Year 2008, Public Law 110–181, amended the Federal Employees' Compensation Act (FECA) by establishing a FECA death gratuity benefit of up to $100,000 for eligible beneficiaries of Federal employees and Non-Appropriated Fund Instrumentality employees who die from injuries incurred in connection with service with an Armed Force in a contingency operation. The OWCP associates three forms with this ICR. Form CA–40 requests information necessary from an employee who chooses to name alternate beneficiaries from those otherwise established by law. Form CA–41 provides the means for those named beneficiaries to file benefit claims. Information provided by such claimants allows the OWCP to determine payment eligibility. The statute and regulations also require Agencies to notify the OWCP immediately upon the death of a covered employee, and Form CA–42 provides the means to accomplish this notification. This latter form requests information necessary to administer any claim for benefits resulting from such a death. The Federal Employee Compensation Act authorizes this information collection. *See* 5 U.S.C. 8145, 8149.

This information collection has been classified as a revision, because of changes to the forms. For example, each form has enhanced the statement informing respondents with disabilities how they may obtain assistance in filing a claim. A certification on Form CA–41 has also been clarified and direct deposit information has been added.

This information collection is subject to the PRA. A Federal agency generally cannot conduct or sponsor a collection of information, and the public is generally not required to respond to an information collection, unless it is approved by the OMB under the PRA and displays a currently valid OMB Control Number. In addition, notwithstanding any other provisions of law, no person shall generally be subject to penalty for failing to comply with a collection of information that does not display a valid Control Number. *See* 5 CFR 1320.5(a) and 1320.6. The DOL obtains OMB approval for this information collection under Control Number 1240–0017. The current approval is scheduled to expire on August 31, 2016; however, the DOL notes that existing information collection requirements submitted to the OMB receive a month-to-month extension while they undergo review. New requirements would only take effect upon OMB approval. For additional substantive information about this ICR, see the related notice published in the **Federal Register** on April 13, 2016 (81 FR 21905).

Interested parties are encouraged to send comments to the OMB, Office of Information and Regulatory Affairs at the address shown in the **ADDRESSES** section within thirty (30) days of publication of this notice in the **Federal Register**. In order to help ensure appropriate consideration, comments should mention OMB Control Number 1240–0017. The OMB is particularly interested in comments that:

- Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;
- Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;
- Enhance the quality, utility, and clarity of the information to be collected; and
- Minimize the burden of the collection of information on those who are to respond, including through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses.

Agency: DOL–OWCP.

Title of Collection: Death Gratuity.

OMB Control Number: 1240–0017.

Affected Public: Individuals or Households.

Total Estimated Number of Respondents: 262.

Total Estimated Number of Responses: 262.

Total Estimated Annual Time Burden: 67 hours.

Total Estimated Annual Other Costs Burden: $0.

Dated: August 10, 2016.

Michel Smyth,

Departmental Clearance Officer.

[FR Doc. 2016–19614 Filed 8–16–16; 8:45 am]

BILLING CODE 4510–CH–P

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

Notice of Centennial Challenges Space Robotics Challenge

AGENCY: National Aeronautics and Space Administration (NASA).

NOTICE: (16–056).

ACTION: Notice of Centennial Challenges Space Robotics Challenge.

SUMMARY: This notice is issued in accordance with 51 U.S.C. 20144(c). The Space Robotics Challenge is open and teams that wish to compete may now register. Centennial Challenges is a program of prize competitions to stimulate innovation in technologies of interest and value to NASA and the nation. The Space Robotics Challenge is a prize competition with a $1,000,000 total prize purse to be divided among teams that develop software to increase the autonomy of dexterous humanoid robots. Teams will use software to control a simulated R5 to resolve problems in a virtual environment. NASA is providing the prize purse. Space Center Houston in partnership with Nine Sigma will manage the challenge.

DATES: Challenge registration opens August 16, 2016 and will remain open until September 16, 2016.

Other important dates:

September 19, 2016—Qualification Software version 1

November 15, 2016—Qualification Deadline

December 1, 2016—Qualification Results Announced

June 13–16, 2017—Virtual Competition

ADDRESSES: The Space Robotics Challenge is a virtual competition. The qualification rounds will take place at participant labs and the final competition will take place at Space Center Houston/Johnson Space Center.

FOR FURTHER INFORMATION CONTACT: To register for or get additional information regarding the Space Robotics Challenge, please visit: *www.spaceroboticschallenge.com.*

For general information on the NASA Centennial Challenges Program please visit: *http://www.nasa.gov/challenges.* General questions and comments regarding the program should be addressed to Monsi Roman, Centennial Challenges Program, NASA Marshall Space Flight Center Huntsville, AL 35812. Email address: *hq-stmd-centennialchallenges@mail.nasa.gov.*

SUPPLEMENTARY INFORMATION:

Summary

The following virtual challenge scenario serves as a backdrop for developing coding advancements that enable the autonomy of humanoid robotics:

In the not too distant future, R5 as arrived on Mars along with supplies ahead of a human mission. Overnight a dust storm damaged the habitat and solar array, and caused the primary communication antenna to become misaligned. R5 must now repair an air leak in the habitat, deploy a new solar panel, and align the communication antenna.

Teams will use software to control a simulated R5 in order to resolve the problems caused by the dust storm. Each team will be evaluated according to a scoring metric that considers the number of tasks completed and the time required to complete the tasks.

The competition arena will contain a rover, solar panels, communication dish, and a habitat on a Martian plain. Each component will be within eyesight and walking distance of each other. Practice environments, similar to those used in the final competition, will be provided to teams.

I. Prize Amounts

The total Space Robotics prize purse is $1,000,000 (one million U.S. dollars).

$100,000 Engagement Challenge

$300,000 Qualifying round (The top 20 qualifying teams will receive $15,000 each)

$600,000 Virtual Competition with prizes as follows:

First place: $125,000

Second place: $100,000

Third Place: $50,000

Fourth Place: $25,000

$50,000 bonus prizes awarded to as many as 6 teams

II. Eligibility

To be eligible to win a prize, competitors must;

(1) Register and comply with all requirements in the rules and Team Agreement;

(2) In the case of a private entity, shall be incorporated in and maintain a primary place of business in the United States, and in the case of an individual, whether participating singly or in a group, shall be a citizen or permanent resident of the United States; and

(3) Not be a Federal entity or Federal employee acting within the scope of their employment.

III. Rules

The complete rules for the Space Robotics Challenge can be found at: *www.spaceroboticschallenge.com.*

Cheryl Parker,

NASA Federal Register Liaison Officer.

[FR Doc. 2016–19627 Filed 8–16–16; 8:45 am]

BILLING CODE 7510–13–P

NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

National Endowment for the Arts

Arts Advisory Panel Meetings

AGENCY: National Endowment for the Arts, National Foundation on the Arts and Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the Federal Advisory Committee Act, as amended, notice is hereby given that one meeting of the Arts Advisory Panel to the National Council on the Arts will be held by teleconference.

DATES: All meetings are Eastern time and ending times are approximate: *International* (review of applications): This meeting will be closed. *Date and time:* September 7, 2016; 10:00 a.m. to 11:00 a.m.

ADDRESSES: National Endowment for the Arts, Constitution Center, 400 7th St. SW., Washington, DC, 20506.

FOR FURTHER INFORMATION CONTACT: Further information with reference to these meetings can be obtained from Ms. Kathy Plowitz-Worden, Office of Guidelines & Panel Operations, National Endowment for the Arts, Washington, DC, 20506; *plowitzk@arts.gov,* or call 202/682–5691.

SUPPLEMENTARY INFORMATION: The closed portions of meetings are for the purpose of Panel review, discussion, evaluation, and recommendations on financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including information given in confidence to the agency. In accordance with the determination of the Chairman of July 5, 2016, these sessions will be closed to the public pursuant to subsection (c)(6) of section 552b of title 5, United States Code.

Dated: August 12, 2016.

Kathy Plowitz-Worden,

Panel Coordinator, National Endowment for the Arts.

[FR Doc. 2016–19644 Filed 8–16–16; 8:45 am]

BILLING CODE 7537–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2014–0203]

Conduct of Operations

AGENCY: Nuclear Regulatory Commission.

ACTION: Standard review plan—final section revision; final issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing final revisions to the following sections in Chapter 13, "Conduct of Operations," of NUREG–0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants: LWR Edition": Section 13.1.1, "Management and Technical Support Organization"; Section 13.1.2–13.1.3, "Operating Organization"; Section 13.2.1, "Reactor Operator Requalification Program; Reactor Operator Training"; Section 13.2.2, "Non-licensed Plant Staff Training"; and Section 13.5.1.1, "Administrative Procedures—General."

DATES: The effective date of this Standard Review Plan (SRP) update is September 16, 2016.

ADDRESSES: Please refer to Docket ID NRC–2014–0203 when contacting the NRC about the availability of information regarding this document. You may access publicly-available information related to this document using any of the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2014–0203. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly-available documents online in the ADAMS Public Documents collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "Begin Web-based ADAMS Search." For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* For the convenience of the reader, the ADAMS accession numbers are provided in a table in the "Availability of Documents" section of this document.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.
- The NRC posts its issued staff guidance on the NRC's external Web page (*http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr0800/*).

FOR FURTHER INFORMATION CONTACT: Mark D. Notich, Office of New Reactors, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001; telephone: 301–415–3053; email: *Mark.Notich@nrc.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On September 24, 2014 (79 FR 57141), the NRC published for public comment the proposed revisions to Chapter 13 of the SRP. A summary of the comments and the NRC staff's disposition of the comments are available in a separate document, "Public Comment Response Table SRP Section 13.1.1 through 13.5.1.1" (ADAMS Accession No. ML15008A024).

The Office of New Reactors is revising these sections from their current versions. Details of specific changes in the proposed revisions are included at the end of each of the proposed sections.

The changes to this SRP chapter reflect NRC staff's current review methods and practices based on lessons learned from the NRC's reviews of design certification and combined license applications completed since the last revision of this chapter.

II. Backfitting and Issue Finality

Issuance of these revised SRP sections does not constitute backfitting as defined in § 50.109 of title 10 of the *Code of Federal Regulations* (10 CFR), "Backfitting," (the Backfit rule) or otherwise be inconsistent with the issue finality provisions in 10 CFR part 52. The NRC's position is based upon the following considerations:

1. *The SRP positions would not constitute backfitting, inasmuch as the SRP is internal guidance directed at the NRC staff with respect to their regulatory responsibilities.*

The SRP provides guidance to the NRC staff on how to review an application for NRC's regulatory approval in the form of licensing. Changes in internal staff guidance are not matters for which either nuclear power plant applicants or licensees are protected under either the Backfit Rule or the issue finality provisions of 10 CFR part 52.

2. *The NRC staff has no intention to impose the SRP positions on existing licensees either now or in the future.*

The staff does not intend to impose or apply the positions described in the SRP to existing (already issued) licenses and regulatory approvals. Therefore, the issuance of a final SRP—even if considered guidance that is within the purview of the issue finality provisions in 10 CFR part 52—need not be evaluated as if it were a backfit or as being inconsistent with issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP on holders of already issued licenses in a manner which does not provide issue finality as described in the applicable issue finality provision, then the staff must make the showing as set forth in the Backfit Rule or address the criteria for avoiding issue finality as described in the applicable issue finality provision.

3. *Backfitting and issue finality do not—with limited exceptions not applicable here—protect current or future applicants.*

Applicants and potential applicants are not, with certain exceptions, protected by either the Backfit Rule or any issue finality provisions under 10 CFR part 52. This is because neither the Backfit Rule nor the issue finality provisions under 10 CFR part 52—with certain exclusions discussed in the next paragraph—were intended to apply to every NRC action that substantially changes the expectations of current and future applicants.

The exceptions to the general principle are applicable whenever an applicant references a 10 CFR part 52 license (*e.g.,* an early site permit) and/or NRC regulatory approval (*e.g.,* a design certification rule) with specified issue finality provisions. The staff does not, at this time, intend to impose the positions represented in the SRP in a manner that is inconsistent with any issue finality provisions. If, in the future, the staff seeks to impose a position in the SRP in a manner that does not provide issue finality as described in the applicable issue finality provision, then the staff must address the criteria for avoiding issue finality as described in the applicable issue finality provision.

III. Availability of Documents

The documents identified in the following table are available to interested persons.

SRP Section	Current version	Final revision	Redline strikeout
13.1.1	ML13311B662	ML15005A449	ML16078A165
13.1.2–13.1.3	ML13311B719	ML15007A296	ML16081A063
13.2.1	ML13311B565	ML15006A035	ML16081A014
13.2.2	ML14030A091	ML15006A129	ML16081A022
13.5.1.1	ML13115A067	ML15006A205	ML16078A352

IV. Congressional Review Act

In accordance with the Congressional Review Act, the NRC has determined that this action is not a major rule and has verified this determination with the Office of Information and Regulatory Affairs of the Office of Management and Budget.

Dated at Rockville, Maryland, this 11th day of August, 2016.

For the Nuclear Regulatory Commission.

Joseph Colaccino,

Chief, New Reactor Rulemaking and Guidance Branch, Division of Engineering, Infrastructure, and Advanced Reactors, Office of New Reactors.

[FR Doc. 2016–19562 Filed 8–16–16; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[NRC–2012–0152]

Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Normal Atmosphere Cleanup Systems in Light Water Cooled Nuclear Power Plants

AGENCY: Nuclear Regulatory Commission.

ACTION: Regulatory Guide; Issuance.

SUMMARY: The U.S. Nuclear Regulatory Commission (NRC) is issuing Revision 3 to Regulatory Guide (RG) 1.140, "Design, Inspection, and Testing Criteria for Air Filtration and Adsorption Units of Normal Atmosphere Cleanup Systems in Light Water Cooled Nuclear Power Plants." This RG describes a method that the NRC staff considers acceptable to implement regulatory requirements with regard to the design, inspection, and testing of normal atmosphere cleanup systems for controlling releases of airborne radioactive materials to the environment during normal operations, including anticipated operational occurrences. This guide applies to all types of nuclear power plants that use water as the primary means of cooling.

DATES: Revision 3 to RG 1.140 is available on August 17, 2016.

ADDRESSES: Please refer to Docket ID NRC–2012–0152 when contacting the NRC about the availability of information regarding this document. You may obtain publicly available information related to this document, using the following methods:

- *Federal Rulemaking Web site:* Go to *http://www.regulations.gov* and search for Docket ID NRC–2012–0152. Address questions about NRC dockets to Carol Gallagher; telephone: 301–415–3463; email: *Carol.Gallagher@nrc.gov.* For technical questions, contact the individuals listed in the **FOR FURTHER INFORMATION CONTACT** section of this document.
- *NRC's Agencywide Documents Access and Management System (ADAMS):* You may obtain publicly available documents online in the ADAMS Public Document collection at *http://www.nrc.gov/reading-rm/adams.html.* To begin the search, select "ADAMS Public Documents" and then select "*Begin Web-based ADAMS Search.*" For problems with ADAMS, please contact the NRC's Public Document Room (PDR) reference staff at 1–800–397–4209, 301–415–4737, or by email to *pdr.resource@nrc.gov.* The ADAMS accession number for each document referenced (if that document is available in ADAMS) is provided the first time that a document is referenced. Revision 3 to RG 1.140, and the regulatory analysis are available in ADAMS under Accession No. ML16070A277 and ML16082A538, respectively.
- *NRC's PDR:* You may examine and purchase copies of public documents at the NRC's PDR, Room O1–F21, One White Flint North, 11555 Rockville Pike, Rockville, Maryland 20852.

Regulatory guides are not copyrighted, and NRC approval is not required to reproduce them.

FOR FURTHER INFORMATION CONTACT: Jerome Bettle, Office of Nuclear Reactor Regulation, telephone: 301–415–1314, email: *Jerome.Bettle@nrc.gov;* and Stephen Burton, Office of Nuclear Regulatory Research, telephone: 301–415–7000, email: *Stephen.Burton@nrc.gov:* Both are staff of the U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001.

SUPPLEMENTARY INFORMATION:

I. Introduction

The NRC is issuing a revision to an existing guide in the NRC's "Regulatory Guide" series. This series was developed to describe and make available to the public information regarding methods that are acceptable to the NRC staff for implementing specific parts of the agency's regulations, techniques that the NRC staff uses in evaluating specific issues or postulated events, and data that the NRC staff needs in its review of applications for permits and licenses.

Revision 3 of RG 1.140 was issued with a temporary identification of Draft Regulatory Guide, DG–1280. Since the NRC issued Revision 2 of RG 1.140, in June 2001, the American Society of Mechanical Engineers (ASME) Committee on Nuclear Air and Gas Treatment (CONAGT) has revised and expanded the scope of equipment covered by ASME–AG–1, "Code on Nuclear Air and Gas Treatment," which the staff previously endorsed in RG 1.140. The revision to ASME–AG–1b consolidated some requirements from ASME–N509, "Nuclear Power Plant Air Cleaning Units and Components"; ASME–N510, "Testing of Nuclear Air-Treatment Systems"; and other documents previously endorsed by the staff in RG 1.140. In addition, CONAGT has developed and published a new standard, ASME N511–2007, "Inservice Testing of Nuclear Air Treatment, Heating Ventilation and Air Conditioning Systems." This new standard provides comprehensive test and inspection requirements and is written to complement the expanded ASME–AG–1b. Therefore, this guide was revised to address these changes to the referenced industry standards.

II. Additional Information

The DG–1280, was published in the **Federal Register** on June 29, 2012 (77 FR 38857), for a 60-day public comment period. The public comment period closed on August 27, 2012. Public comments on DG–1280 and the NRC staff responses to the public comments are available in ADAMS under Accession No. ML16070A279.

III. Congressional Review Act

This regulatory guide is a rule as defined in the Congressional Review Act (5 U.S.C. 801–808). However, the Office of Management and Budget has not found it to be a major rule as defined in the Congressional Review Act.

IV. Backfitting and Issue Finality

Revision 3 of RG 1.140 describes a method that the NRC staff considers acceptable to implement regulatory requirements with regard to the design, inspection, and testing of normal atmosphere cleanup systems for controlling releases of airborne radioactive materials to the environment during normal operations, including anticipated operational occurrences. Issuance of this RG does not constitute backfitting as defined in 10 CFR 50.109 (the Backfit Rule) and is not otherwise inconsistent with the issue finality provisions in 10 CFR part 52. As discussed in the ''Implementation'' section of this RG, the NRC has no current intention to impose this RG on holders of current operating licenses or combined licenses.

This RG may be applied to applications for operating licenses, combined licenses, early site permits, and certified design rules docketed by the NRC as of the date of issuance of the final regulatory guide, as well as future applications submitted after the issuance of the regulatory guide. Such action would not constitute backfitting as defined in the Backfit Rule or be otherwise inconsistent with the applicable issue finality provision in 10 CFR part 52, inasmuch as such applicants or potential applicants are not within the scope of entities protected by the Backfit Rule or the relevant issue finality provisions in part 52.

Dated at Rockville, Maryland, this 11th day of August, 2016.

For the Nuclear Regulatory Commission.

Thomas H. Boyce,

Chief, Regulatory Guidance and Generic Issues Branch, Division of Engineering, Office of Nuclear Regulatory Research.

[FR Doc. 2016–19559 Filed 8–16–16; 8:45 am]

BILLING CODE 7590–01–P

OVERSEAS PRIVATE INVESTMENT CORPORATION

Sunshine Notice—September 7, 2016 Public Hearing

TIME AND DATE: 2:00 p.m., Wednesday, September 7, 2016.

PLACE: Offices of the Corporation, Twelfth Floor Board Room, 1100 New York Avenue NW., Washington, DC.

STATUS: Hearing OPEN to the Public at 2:00 p.m.

PURPOSE: Public Hearing in conjunction with each meeting of OPIC's Board of Directors, to afford an opportunity for any person to present views regarding the activities of the Corporation.

PROCEDURES: Individuals wishing to address the hearing orally must provide advance notice to OPIC's Corporate Secretary no later than 5:00 p.m. Wednesday, August 31, 2016. The notice must include the individual's name, title, organization, address, and telephone number, and a concise summary of the subject matter to be presented.

Oral presentations may not exceed ten (10) minutes. The time for individual presentations may be reduced proportionately, if necessary, to afford all participants who have submitted a timely request an opportunity to be heard.

Participants wishing to submit a written statement for the record must submit a copy of such statement to OPIC's Corporate Secretary no later than 5:00 p.m. Wednesday, August 31, 2016. Such statement must be typewritten, double spaced, and may not exceed twenty-five (25) pages.

Upon receipt of the required notice, OPIC will prepare an agenda, which will be available at the hearing, that identifies speakers, the subject on which each participant will speak, and the time allotted for each presentation.

A written summary of the hearing will be compiled, and such summary will be made available, upon written request to OPIC's Corporate Secretary, at the cost of reproduction.

Written summaries of the projects to be presented at the September 15, 2016 Board meeting will be posted on OPIC's Web site.

CONTACT PERSON FOR INFORMATION: Information on the hearing may be obtained from Catherine F. I. Andrade at (202) 336–8768, via facsimile at (202) 408–0297, or via email at *Catherine.Andrade@opic.gov.*

Dated: August 12, 2016.

Catherine F. I. Andrade,

OPIC Corporate Secretary.

[FR Doc. 2016–19630 Filed 8–15–16; 4:15 pm]

BILLING CODE 3210–01–P

RAILROAD RETIREMENT BOARD

Proposed Collection; Comment Request

SUMMARY: In accordance with the requirement of Section 3506 (c)(2)(A) of the Paperwork Reduction Act of 1995 which provides opportunity for public comment on new or revised data collections, the Railroad Retirement Board (RRB) will publish periodic summaries of proposed data collections.

Comments are invited on: (a) Whether the proposed information collection is necessary for the proper performance of the functions of the agency, including whether the information has practical utility; (b) the accuracy of the RRB's estimate of the burden of the collection of the information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden related to the collection of information on respondents, including the use of automated collection techniques or other forms of information technology.

1. *Title and purpose of information collection:* Application to Act as Representative Payee; OMB 3220–0052.

Under Section 12 of the Railroad Retirement Act, the Railroad Retirement Board (RRB) may pay benefits to a representative payee when an employee, spouse or survivor annuitant is incompetent or is a minor. A representative payee may be a court-appointed guardian, a statutory conservator or an individual selected by the RRB. The procedures pertaining to the appointment and responsibilities of a representative payee are prescribed in 20 CFR 266.

The forms furnished by the RRB to apply for representative payee status, and for securing the information needed to support the application follow. RRB Form AA–5, *Application for Substitution of Payee,* obtains information needed to determine the selection of a representative payee who will serve in the best interest of the beneficiary. RRB Form G–478, *Statement Regarding Patient's Capability to Manage Benefits,* obtains information about an annuitant's capability to manage their own benefits. The form is completed by the annuitant's personal physician or by a medical officer, if the annuitant is in an institution. It is not required when a court has appointed an individual or institution to manage the annuitant's funds or, in the absence of such appointment, when the annuitant is a minor. The RRB also provides representative payees with a booklet at the time of their appointment. The booklet, RRB Form RB–5, *Your Duties as Representative Payee-Representative Payee's Record,* advises representative payees of their responsibilities under 20 CFR 266.9 and provides a means for the representative payee to maintain records pertaining to the receipt and use of RRB benefits. The booklet is provided for the representative payee's convenience. The RRB also accepts records that are kept by representative payee's as part of a common business practice. Completion is voluntary. One response is requested of each respondent.

The RRB is proposing non-burden impacting editorial changes to Forms AA–5, G–478, and the RB–5 booklet.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form number	Annual responses	Time (minutes)	Burden (hours)
AA–5	*3,000*		*850*
Individuals	2,250	17	637.5
Institutions	750		212.5
G–478	2,000	6	200.0
RB–5	*15,300*		*15,300*
Individuals	11,475	60	11,475
Institutions	3,825		3,825
Total	20,300		16,350

2. Employer Service and Compensation Reports; OMB 3220–0070.

Section 2(c) of the Railroad Unemployment Insurance Act (RUIA) specifies the maximum normal unemployment and sickness benefits that may be paid in a benefit year. Section 2(c) further provides for extended benefits for certain employees and for beginning a benefit year early for other employees. The conditions for these actions are prescribed in 20 CFR 302.

All information about creditable railroad service and compensation needed by the RRB to administer Section 2(c) is not always available from annual reports filed by railroad employers with the RRB (OMB 3220–0008). When this occurs, the RRB must obtain supplemental information about service and compensation.

The RRB utilizes Form UI–41, *Supplemental Report of Service and Compensation,* and Form UI–41a, *Supplemental Report of Compensation,* to obtain the additional information about service and compensation from railroad employers. Completion of the forms is mandatory. One response is required of each respondent. The RRB proposes no changes to Form UI–41 and UI–41a.

ESTIMATE OF ANNUAL RESPONDENT BURDEN

Form number	Annual responses	Time (minutes)	Burden (hours)
UI–41	100	8	13
UI–41a	50	8	7
Total	150		20

Additional Information or Comments: To request more information or to obtain a copy of the information collection justification, forms, and/or supporting material, contact Dana Hickman at (312) 751–4981 or *Dana.Hickman@RRB.GOV.* Comments regarding the information collection should be addressed to Charles Mierzwa, Railroad Retirement Board, 844 North Rush Street, Chicago, Illinois 60611–2092 or emailed to *Charles.Mierzwa@RRB.GOV.* Written comments should be received within 60 days of this notice.

Charles Mierzwa,

Chief of Information Resources Management.

[FR Doc. 2016–19606 Filed 8–16–16; 8:45 am]

BILLING CODE 7905–01–P

SECURITIES AND EXCHANGE COMMISSION

[File No. 500–1]

In the Matter of Neuromama, Ltd.; Order of Suspension of Trading

August 15, 2016.

It appears to the Securities and Exchange Commission that the public interest and the protection of investors require a suspension of trading in the securities of Neuromama, Ltd, Inc. (CIK No. 0001542918) because of concerns regarding the accuracy and adequacy of information in the marketplace about, among other things, the identity of the persons in control of the company's operations and management, false statements to company shareholders and/or potential investors that the company has an application pending for listing on the NASDAQ Stock Market, and potentially manipulative transactions in the company's stock. Neuromama, Ltd. is a Nevada corporation with its principal place of business listed as Playas de Rosarito, Baja California, Mexico, with stock quoted on OTC Link (previously ''Pink Sheets'') operated by OTC Markets Group, Inc. under the ticker symbol NERO.

The Commission is of the opinion that the public interest and the protection of investors require a suspension of trading in the securities of the above-listed company.

THEREFORE, IT IS ORDERED, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that trading in the securities of the above-listed company is suspended for the period from 9:30 a.m. EDT, on August 15, 2016, through 11:59 p.m. EDT, on August 26, 2016.

By the Commission.

Lynn M. Powalski,

Deputy Secretary.

[FR Doc. 2016–19718 Filed 8–15–16; 4:15 pm]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78549; File No. SR–FINRA–2016–029]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Amending the Code of Arbitration Procedure for Customer Disputes and the Code of Arbitration Procedure for Industry Disputes to Require All Parties Other Than *Pro Se* Customers To File and Serve Pleadings and Documents Through the FINRA Office of Dispute Resolution's Party Portal and To Permit Mediation Parties To Use the Portal

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act" or "Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 27, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend the Code of Arbitration Procedure for Customer Disputes ("Customer Code") and the Code of Arbitration Procedure for Industry Disputes ("Industry Code" and, together with the Customer Code, "Codes"), to require all parties, except customers who are not represented by an attorney or other person ("*pro se* customers"), to use the FINRA Office of Dispute Resolution's Party Portal ("Party Portal") to file initial statements of claim and to file and serve pleadings and other documents on FINRA or any other party. Under the proposed rule change, FINRA would require parties to use the Party Portal to file and serve correspondence relating to discovery requests, but would not permit parties to file documents produced in response to discovery requests through the Party Portal. FINRA is also proposing to amend the Code of Mediation Procedure ("Mediation Code") to permit mediation parties to agree to use the Party Portal to submit and retrieve all documents and other communications. In addition, FINRA is revising other provisions in the Codes to conform to existing practice.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

In 2004, FINRA implemented an online, web-based arbitration claim notification and filing system that allowed a claimant[3] or claimant's counsel to file voluntarily an arbitration claim through that system ("online claim filing system").[4] Currently, the Codes allow a claimant to file a claim[5] either in hard copy or by using the online claim filing system.[6] The online claim filing system allows a claimant to complete forms, submit documents, and pay filing fees online. Some of the benefits of using the online claim filing system are that claims are filed and processed more quickly, and the burden of using hard-copy documents by parties and staff is significantly reduced.

In June 2013, FINRA introduced a separate secure, online service called the Dispute Resolution Portal ("DR Portal") to facilitate interactions among parties, arbitrators, mediators, and FINRA staff on arbitration case-related matters. As further discussed below, the DR Portal includes both a Party Portal and an Arbitrator and Mediator Portal. The Party Portal uses an invitation/registration process that provides a secure way to send and receive arbitration and mediation case documents. As soon as a party notifies FINRA of the name of the person who should be given access to the arbitration or mediation case file (typically the party's representative), FINRA sends an email to the named person with an invitation to register on the Party Portal via a personalized Web address link that provides complete access to the specified case. This invitation/registration process ensures that FINRA maintains a case specific level of security and access within the Party Portal. Once registered, the representative can provide other individuals (such as legal assistants and co-counsel) with access to appropriate cases on the Party Portal.

FINRA initially opened the Party Portal to a small number of firms to gain experience with the technology and to incorporate user feedback. Over time, FINRA expanded access to the Party Portal, and as of July 20, 2015, FINRA allowed all parties to use the Party Portal voluntarily in all arbitration and mediation cases filed as of that date. Through the Party Portal, parties can, among other things, receive documents from and send documents to FINRA, receive service[7] of a claim, submit an answer to a claim, submit additional case documents, view the status of a case, and select arbitrators.

FINRA staff solicited feedback and received suggestions from users on how to enhance the Party Portal's functionality. Through a series of quarterly releases, FINRA has upgraded the Party Portal to allow parties to, among other things, schedule hearings, receive automated messages when new documents are posted, see an indication of received documents not yet viewed, and send documents to other Party Portal case participants. FINRA received positive feedback on the Party Portal from parties who used the system voluntarily. In light of the positive user feedback and the various enhancements that FINRA has made to the system since implementing the Party Portal, FINRA believes that it would be appropriate to require parties, with limited exceptions, to use the Party Portal on a mandatory basis.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Rules 12100(e) and 13100(e). The term "claimant" means a party that files the statement of claim that initiates an arbitration proceeding.

[4] *See Notice to Members* 04–56.

[5] *See* Rules 12302(a) and 13302(a).

[6] *See* FINRA, Arbitration Online Claim Filing, available at *http://www.finra.org/arbitration-and-mediation/online-claim-filing.*

[7] Service is the process of delivering a pleading (*e.g.*, the statement of claim or answer) or other documents to the opposing party.

The Arbitrator and Mediator Portal is open to all FINRA arbitrators and mediators to use on a voluntary basis. In this Portal, arbitrators and mediators can view and update their profile and disclosure information, access information about their assigned cases, schedule hearing dates, and view case documents. FINRA has encouraged arbitrators and mediators to register to use the Arbitrator and Mediator Portal because it enhances efficiencies at the forum. Currently, 74 percent of arbitrators and 85 percent of mediators available to serve on cases have registered to use the Arbitrator and Mediator Portal.

Proposed Rule Change

FINRA is proposing to require parties to use the Party Portal to submit documents and view their arbitration case information and documents in most instances. There would be an exception for *pro se* customers.[8] FINRA would invite *pro se* customers to use the Party Portal, but would not require them to do so. However, if a *pro se* customer files a claim using the Party Portal, then FINRA would require the customer to use the Party Portal for the duration of the arbitration process.

FINRA would require parties to use the Party Portal to file and serve correspondence relating to discovery requests, but would not permit parties to file documents produced in response to discovery requests through the Party Portal. FINRA believes that maintaining the correspondence in the Party Portal makes sense because it is part of the case record. However, depending on the subject of a case, discovery production can be voluminous, and FINRA does not believe it would be efficient for the Party Portal to be used as the receptacle for parties' exchanged discovery. This approach is consistent with our current practice.

Finally, under the proposed rule change, since mediation is voluntary in all instances, FINRA would permit parties to a mediation proceeding to use the Party Portal on a voluntary basis to submit and view their mediation case information and documents.

FINRA is proposing to amend each of the rules in the Codes affected by required use of the Party Portal. The changes would update the rule language to reflect how parties comply with the Codes through use of the Party Portal. FINRA Rules 12300 and 13300 describe how parties file pleadings[9] and documents with FINRA and serve pleadings and documents on other parties through the Party Portal. The terms "file" and "serve"—terms associated with use of the Party Portal—are used throughout the Codes. Under the proposed rule change, when a party submits pleadings or documents through the Party Portal, the party has accomplished both filing with the Director[10] and, in most instances, service on all other parties and the arbitrators.[11] Therefore, in most of the proposed rule amendments, FINRA would delete references to parties filing pleadings and documents with the Director at the same time as on other parties, and providing copies for arbitrators.

For reader convenience, the discussion below only details the proposed changes to the FINRA rules in the Customer Code. However, FINRA is proposing to make substantively similar amendments to the Industry Code. The primary difference between the proposed amendments to the Customer Code and the Industry Code is that the Customer Code provides an exemption from required use of the Party Portal for *pro se* customers. The Industry Code would not provide an exemption for any party.

As a result of the proposed rule change, FINRA would need to update several cross-references in the Codes. The proposed updates are noted as applicable. In addition, forum users have indicated that for ease of citation, they would prefer that FINRA use numbers and letters instead of bullets. Therefore, FINRA is proposing to replace bullets with numbers or letters in each of the rules affected by the proposed rule change. The proposed replacements are noted where applicable.

In addition to changes in the Codes, FINRA is proposing to amend the Mediation Code to permit parties to agree to use the Party Portal to submit and retrieve all documents and other communications and to view mediation case information. The proposed amendments are discussed below.

Customer Code

FINRA Rule 12100—Definitions

FINRA is proposing to amend FINRA Rule 12100 to add new definitions and to amend several definitions in the Customer Code relating to the required use of the Party Portal.

Arbitrator and Mediator Portal—FINRA is proposing to add a new definition to the rule to define "Arbitrator and Mediator Portal" as the web-based system that allows invited arbitrators and mediators to access a secure section of FINRA's Web site to submit documents and information and to view their arbitration and mediation case information and documents.[12]

Claim Notification Letter—FINRA is proposing to add a new definition to the rule to define "Claim Notification Letter" as the notice that FINRA would send respondents indicating that they have been named as a party in a statement of claim.[13] The new definition would specify that the Claim Notification Letter will provide information about accessing the Party Portal to obtain a copy of the statement of claim filed by the claimants and information about the arbitration, including the hearing location selected by the Director and the deadline for filing a statement of answer.

Day—In the current rule, FINRA defines the term "day" as a calendar day.[14] The definition provides that if a deadline specified in the Code falls on a Saturday, Sunday or any FINRA holiday, the deadline is extended until the next business day. Under the proposed rule change, other than the statement of claim, which FINRA serves upon all respondents, parties will be able to serve documents on each other through the Party Portal on any day and at any time. Service would occur immediately after FINRA receives a document, regardless of the day or time of receipt. If, for example, a party submits a document on a Saturday, the Party Portal will immediately transmit the documents to the appropriate parties on that day. Certain deadlines in the Code are triggered by a party's receipt of a pleading.[15] FINRA does not believe it would be appropriate to trigger a deadline based on an opposing party's weekend use of the Party Portal. Therefore, FINRA is proposing to amend the definition of "day" to clarify that if a party receives pleadings or other documents on a Saturday, Sunday or any FINRA holiday, the date of receipt shall be the next business day.

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[8] FINRA would define *pro se* in the Customer Code as a party that is not represented by an attorney or others during an arbitration or mediation. FINRA would not define *pro se* in the Industry Code. Under the proposed rule change, FINRA would not exempt *pro se* parties from the requirement under the Industry Code to submit documents through the Party Portal.

[9] FINRA Rule 12100 defines a pleading as "a statement describing a party's causes of action or defense. Documents that are considered pleadings are: a statement of claim, an answer, a counterclaim, a cross claim, a third party claim, and any replies."

[10] The Director refers to the FINRA Office of Dispute Resolution Director as described in FINRA Rule 12103 (Director of Dispute Resolution).

[11] For example, FINRA Rule 12304 (Answering Counterclaims) currently provides that a claimant must directly serve any answer to a counterclaim on each other party and at the same time must file the answer to the counterclaim with the Director with additional copies for the arbitrator. Under the proposed rule change, as described further in the discussion, once the claimant submits the answer through the Party Portal, the claimant has also filed the answer with the Director.

[12] *See* proposed FINRA Rule 12100(a).

[13] *See* proposed FINRA Rule 12100(f).

[14] *See* FINRA Rule 12100(j).

Non-Public Arbitrator—FINRA is proposing to amend the definition of non-public arbitrator[16] to update cross-references in the rule.

Party Portal—FINRA is proposing to add a new definition to the rule to define "Party Portal" as the web-based system that is accessible by arbitration and mediation parties and their representatives. The Party Portal allows invited participants to access a secure section of FINRA's Web site to submit documents and view their arbitration and mediation case information and documents.[17]

Pro Se—FINRA is proposing to add a new definition to the rule to define "*Pro Se*" to mean a party that is not represented by an attorney or others during an arbitration or mediation.[18]

Public Arbitrator—FINRA is proposing to amend the definition of Public Arbitrator[19] to update cross-references in the rule.

Finally, FINRA would reletter the definitions to reflect the addition of the new terms.

FINRA Rule 12211—Direct Communication Between Parties and Arbitrators

Subject to specified limitations, FINRA allows parties that are represented by counsel to communicate directly with arbitrators during an arbitration proceeding. FINRA Rule 12211, which outlines the procedures that parties and arbitrators must follow when they agree to direct communication, currently indicates that parties may send items by regular mail, overnight courier, facsimile, or email. Under the proposed rule change, since parties would be required to use the Party Portal for transmitting documents to each other, and would continue to use other methods to send items to the arbitrators, FINRA is proposing to: (1) Amend FINRA Rule 12211(e) to specify that parties are allowed to send items to the arbitrators by first-class mail, overnight mail service, overnight delivery service, hand delivery, email, or facsimile as specified in an order issued by the arbitrators; (2) amend Rule 12211(f) to delete the requirement that the parties send copies of the materials they sent to the arbitrators to each other and the Director at the same time and in the same manner, requiring instead that they serve the materials on each other and filed with the Director through the Party Portal; and (3) amend Rule 12211(g) to clarify that parties must file copies of arbitrator orders and decisions with the Director through the Party Portal.

Rule 12211(b) provides that if at some point during an arbitration a party chooses to appear *pro se,* which the rule defines in a parenthetical as meaning "without counsel," then the rule no longer applies. As stated above, FINRA is proposing to amend Rule 12100 to define *pro se* to mean a party that is not represented by an attorney *or others* during an arbitration or mediation. The new definition of *pro se* in Rule 12100 is inconsistent with the current definition in Rule 12211. Therefore, FINRA is proposing to amend Rule 12211(b) to delete the reference to "*pro se.*" Instead, the rule would provide that if a party chooses to appear without counsel, then the rule would no longer apply.[20]

FINRA Rule 12300—Filing and Serving Documents

FINRA is proposing to delete the content in FINRA Rule 12300 (Filing and Serving Documents) in its entirety and replace it with new language which describes how filing and service, among other things, would operate when FINRA requires parties to use the Party Portal.

Party Portal—New Rule 12300(a)(1) would provide that parties must use the Party Portal to file initial statements of claim and to file and serve pleadings and any other documents on the Director or any other party. The rule would also provide that the Director may exercise authority to permit the use of other means of filing or service in the case of an extended Party Portal outage or in other extraordinary circumstances.[21]

Rule 12300(a)(2) would provide an exemption for *pro se* customers and would outline the procedures for *pro se* customers who do not wish to use the Party Portal. While a *pro se* customer would not be required to take any affirmative steps to opt out of using the Party Portal, if a *pro se* customer files a claim using the Party Portal, then the *pro se* customer must use the Party Portal for the duration of the arbitration process. The Party Portal would include a warning to *pro se* customers that if they file their claim using the online filing facility, they will be required to use the Party Portal for the remainder of the arbitration proceeding.

Concerning *pro se* customers who opt out of using the Party Portal, Rule 12300(a) would provide that they: (1) May file claims and serve documents by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile; (2) must comply with the provisions relating to filing an initial statement of claim outlined in FINRA Rule 12302 (Filing an Initial Statement of Claim); and (3) must provide proof of service for any documents served outside of the Party Portal (except for the initial statement of claim because the Director will serve the Claim Notification Letter or initial statement of claim on the respondents).

FINRA does not want parties to use the Party Portal to submit documents they produce during discovery. Therefore, FINRA is proposing to provide in Rule 12300(a)(3) that parties shall not file with FINRA or serve on any other party, through the Party Portal, documents produced during discovery pursuant to the Rule 12500 Series. Available service methods for such documents are first-class mail, overnight mail service, overnight delivery service, hand delivery, email, or facsimile. This approach is consistent with our current practice.

Filing—New Rule 12300(b) would provide that with the exception of *pro se* customers who opt out of using the Party Portal, parties must file initial statements of claim and all pleadings and other documents with the Director through the Party Portal. This includes pleadings and documents served on *pro se* customers and other parties by other means. The rule would provide that parties must file with the Director any written responses relating to discovery requests under Rules 12506 and 12507, but must not file any of the documents produced in response to discovery requests as provided in Rule 12300(a)(3).

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[15] *See* FINRA Rules 12304 and 12305 for examples of deadlines triggered by receipt of a pleading.

[16] *See* proposed FINRA Rule 12100(r).

[17] *See* proposed FINRA Rule 12100(t).

[18] *See* proposed FINRA Rule 12100(x). FINRA does not define *pro se* in the Industry Code since there would not be an exemption for any *pro se* parties in intra-industry disputes.

[19] *See* proposed FINRA Rule 12100(y).

[20] FINRA is proposing to amend FINRA Rule 13211 to remove the reference to *pro se* in the rule. Although FINRA is not proposing to define *pro se* in the Industry Code, FINRA believes the amendment would add clarity to the rule and avoid forum user confusion since FINRA is proposing to define *pro se* in the Customer Code.

[21] An example of an extraordinary circumstance would be a severe weather event that caused an extended power outage.

The rule would also provide that parties must file arbitrator ranking lists[22] through the Party Portal, and that filing is accomplished on the day of submission through the Party Portal. Filing by first-class mail or overnight mail is accomplished on the date of mailing, and filing by any other means is accomplished on the date of delivery as is provided in the current rules.

Service—New Rule 12300(c) would provide that the Director will serve the Claim Notification Letter or initial statement of claim on the respondents. In practice, this means that as a first step FINRA would serve only the Claim Notification Letter on respondents that are not identified as customers. If a respondent does not access the Party Portal and view the statement of claim, FINRA would contact the respondent and ask if they received the Claim Notification Letter. If the respondent indicates that they did not receive the letter, FINRA staff would offer to serve the statement of claim in another manner such as by email or regular mail to afford the respondent an additional opportunity to receive the statement of claim and instructions on how to access the Party Portal.

Concerning customers, upon receipt of an initial statement of claim, where a customer is a claimant, FINRA would know if the customer is represented by counsel or another person. However, where a customer is a respondent, FINRA would not know if the customer intends to be represented by counsel or any other individual. Therefore, FINRA would serve all customer respondents with the initial statement of claim along with the Claim Notification Letter explaining that parties other than *pro se* customers are required to use the Party Portal, and that *pro se* customers are invited to use the Party Portal.

The Claim Notification Letter would specify that except for *pro se* customers who opt out of using the Party Portal, parties must serve all pleadings and other documents, except as provided in Rule 12300(a)(3) relating to documents produced in discovery, through the Party Portal. It would explain that parties serve *pro se* parties who opt out of using the Party Portal by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. Under the rule, service would be accomplished on the day of submission through the Party Portal, on the date of mailing by first-class mail or overnight mail service,[23] and on the date of delivery by other means. Finally, for documents not served through the Party Portal, parties must provide proof of service to the Director through the Party Portal.

General Rules—FINRA is proposing to incorporate into proposed Rule 12300(d)(1)(A), the current provision in Rule 12300(g)(1) concerning the redaction of personal confidential information. The current provision in Rule 12300(g)(2) specifying that the redaction requirements do not apply to documents that parties exchange with each other and do not file with the Director, or to documents parties submit to a panel at a hearing would be renumbered as Rule 12300(d)(1)(B). The current provision in Rule 12300(g)(3) providing that the redaction requirements do not apply to Simplified Arbitrations would be renumbered as Rule 12300(d)(1)(C).

Finally, new Rule 12300(d)(2) would provide that a party must serve any change of email or mailing address during an arbitration on all other parties and file this information with the Director. The former rule referred only to "address" changes.

FINRA Rule 12301—Service on Associated Persons

FINRA is proposing to amend FINRA Rule 12301 relating to service on associated persons to delete the reference to the Director serving the initial statement of claim on a respondent associated person. As explained above, under the proposed rule change, associated persons who are parties to an arbitration would be required to use the Party Portal. Therefore, FINRA would serve an associated person with a Claim Notification Letter instead of a statement of claim.

In practice, FINRA staff will know if an associated person did not access the Party Portal to view the statement of claim. In such an instance, FINRA would contact the associated person and ask if he or she received the Claim Notification Letter. If the associated person indicates that he or she did not receive the letter, FINRA staff would offer to serve the statement of claim in another manner such as by email or regular mail to afford the respondent an additional opportunity to receive the statement of claim and instructions on how to access the Party Portal.

If a member and an associated person who is currently associated with the member are named as respondents in the same arbitration, and the Director cannot complete service directly on the associated person as described above, then the proposed rule would provide that the Director may serve the member with the Claim Notification Letter on behalf of the associated person.

12302—Filing and Serving an Initial Statement of Claim

FINRA is proposing to amend FINRA Rule 12302 to reflect how: (1) Parties would file an initial statement of claim; (2) parties would submit required fees; and (3) FINRA would serve the initial statement of claim through the Party Portal.

Filing—Since most parties would be required to file an initial statement of claim through the Party Portal as provided in Rule 12300(a), FINRA is proposing to amend Rule 12302(a) to delete the reference to filing documents in hard copy or electronically through the Online Arbitration Claim Filing system. FINRA is also proposing to amend Rule 12302(b) to delete the instruction to parties to file enough copies for the Director, each arbitrator and each other party. Once a party files the initial statement of claim through the Party Portal, FINRA staff would handle service through the Party Portal or Arbitrator and Mediator Portal as applicable. If FINRA needs to provide copies of the documents in another manner, *e.g.,* because a *pro se* customer has opted out of using the Party Portal, or an arbitrator is not using the Arbitrator and Mediator Portal, then FINRA staff would handle reproduction and distribution of the documents.

Fees—FINRA is proposing to amend Rule 12302(c) to require the claimant to pay all required filing fees by credit card or automated clearing house ("ACH") through the Party Portal unless the party is a *pro se* customer who opts out of using the Party Portal. These payment options are currently available to forum users and requiring payment through the Party Portal would make case administration more efficient. FINRA staff would know immediately if a filing was deficient for lack of payment and would not have to ensure that checks that parties submit separately, by U.S. mail or other method, are correctly matched up to statements of claim submitted through the Party Portal.

Service—Currently, Rule 12301(d) provides that unless the statement of claim is deficient, FINRA will send a copy of the Submission Agreement, the statement of claim, and any additional materials the claimant submits, to the other parties and the arbitrators. FINRA is proposing to amend the rule to specify how staff would serve each subset of participants in the arbitration case. Specifically, FINRA would:

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[22] *See* FINRA Rules 12402(d) and 12403(c).

[23] "Overnight mail" service includes, for example, overnight delivery by Federal Express. Common methods parties use at the forum for overnight mail delivery include Federal Express, United Parcel Service, and United States Postal Service. "Other means" includes, for example, hand delivery.

- Send the Claim Notification Letter to all non-customer respondent(s) pursuant to Rule 12302; and
- Send the Claim Notification Letter along with a copy of the Submission Agreement, the statement of claim, and any additional materials filed by the claimant, to each customer respondent. The Director would inform the customer that if the customer is *pro se,* the customer is not required to use the Party Portal; and
- Send a copy of the Submission Agreement, the statement of claim, and any additional materials filed by the claimant to each arbitrator by first-class mail, overnight mail service, overnight delivery service, hand delivery, email, facsimile or through the Arbitrator and Mediator Portal, once the panel has been appointed.

Additional conforming changes—FINRA would amend the title of Rule 12302 to add a reference to "Service" since the rule addresses both filing and service of the initial statement of claim. FINRA is proposing to reletter the rule and to replace the bullets in Rule 12302(a) with numbers.

12303—Answering the Statement of Claim

FINRA is proposing to amend FINRA Rule 12303 to reflect how respondents would answer a statement of claim using the Party Portal.

Since most parties would be required to serve each other through the Party Portal, FINRA would eliminate the instruction in Rule 12303(a) for parties to "directly" serve each other with the executed Submission Agreement and answer. FINRA would amend Rule 12303(b) to provide that if an answer contains a third party claim,[24] a respondent must serve the third party with the answer containing the third party claim and all documents previously served by any party, or sent to the parties by the Director, by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile, and must file proof of service with the Director through the Party Portal. The respondent must file the third party claim with the Director through the Party Portal except as provided in Rule 12300(a)(2). In addition, since parties would file their Submission Agreement and answer through the Party Portal, FINRA would amend Rule 12303(c) to delete the instruction for a party to file sufficient copies for the Director and arbitrators. Finally, FINRA is proposing to replace the bullets in Rule 12303(a) with numbers.

12304—Answering Counterclaims

FINRA is proposing to amend FINRA Rule 12304(a) relating to answering counterclaims to eliminate the instruction for parties to "directly" serve each other with the answer to a counterclaim, as well as the requirement to file sufficient copies for the Director and arbitrators.

12305—Answering Cross Claims

As with answering counterclaims, FINRA is proposing to amend FINRA Rule 12305(a) relating to answering cross claims to eliminate the instruction for parties to "directly" serve each other with the answer to a cross claim, as well as the requirement to file sufficient copies for the Director and arbitrators because filing instructions would be covered by proposed Rule 12300.

12306—Answering Third Party Claims

FINRA is proposing to amend FINRA Rule 12306 to reflect how FINRA would handle a third party claim in the Party Portal.

As explained in the above discussion on Rule 12303, if a respondent's answer contains a third party claim, the respondent serves the third party with the claim and all documents previously served by the parties or filed with FINRA outside of the Party Portal. Once FINRA is notified of the third party claim, FINRA can invite the third party to use the Party Portal.

Since most parties would be using the Party Portal, FINRA would eliminate the instruction in Rule 12306(a) for parties to "directly" serve each other with the executed Submission Agreement and answer. Similarly, FINRA would amend Rule 12306(b) to provide that if an answer to a third party claim also contains a third party claim, a respondent would be required serve the third party with the answer containing the third party claim and all documents previously served by any party, or sent to the parties by the Director, by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile, and must file proof of service with the Director through the Party Portal. In addition, since parties would file their Submission Agreement and answer through the Party Portal, FINRA would amend Rule 12306(c) to delete the instruction for a party to file sufficient copies for the Director and arbitrators. Finally, FINRA is proposing to replace the bullets in Rule 12306(a) with numbers.

12307—Deficient Claims

The Customer Code provides that the Director will not serve any claim that is deficient. FINRA Rule 12307(a) sets forth various reasons that a claim might be deficient. FINRA is proposing to amend Rule 12307(a) to delete a deficiency that would not be applicable in the Party Portal—that claimant did not file the correct number of copies of the Submission Agreement, statement of claim or supporting documents for service on respondents and for the arbitrators. FINRA is also proposing to amend the rule relating to the deficiency concerning a failure to specify the customer's home address at the time of the events giving rise to the dispute. FINRA would replace home address with "city and state," to conform to the current practice.[25]

FINRA is also proposing to replace the bullets in Rule 12307(a) with numbers and to correct cross-references in the Rule.

12309—Amending Pleadings

FINRA Rule 12309 specifies procedures for parties to amend pleadings. Rule 12309(a) applies to amendments made to a statement of claim or any other pleading before FINRA appoints a panel of arbitrators. Rule 12309(c) applies to amendments made to add a party to the case once the ranked arbitrator lists are due to the Director. In both sections, FINRA is proposing to amend the rule to reflect how amendments operate in the Party Portal.

As stated above, Rule 12309(a) describes how parties amend pleadings before FINRA appoints a panel. FINRA is proposing to amend Rule 12309(a) to clarify that panel appointment occurs when the Director sends notice to the parties of the names of the arbitrators on the panel.

FINRA would amend Rule 12309(a)(1) to eliminate the requirement for parties to file sufficient copies of an amended pleading for the arbitrators and other parties, and to provide that the Director will serve either the Claim Notification Letter, or the amended statement of claim, as applicable, under Rules 12300 and 12301. The rule would also provide that if an amended pleading adds a party to the arbitration, the party amending the pleading must serve the new party with the amended pleading and all documents previously served by any party, or sent to the parties by the Director, by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile, and must file proof of service with the Director through the Party Portal. The party amending the pleading must file the amended pleading with the Director through the Party Portal except as provided in Rule 12300(a)(2).

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[24] *See* current Rule 12100(y), which defines "Third Party Claim" to mean a claim asserted against a party not already named in the statement of claim or any other previous pleading.

[25] Industry Code Rule 13307 differs from the Customer Code rule because there is no reference to a customer's home address.

Rule 12309(c) explains that after ranked arbitrator lists are due to the Director, parties may not amend the pleadings to add new parties until FINRA appoints a panel and the panel grants a motion to add a new party. Motions to add a party after panel appointment must be served on all parties, including the party that is the subject of the motion. The process for serving the new party under Rule 12309(c) is the same as it is in Rule 12309(a). FINRA is proposing to amend Rule 12309(c) to provide that the party seeking to amend the pleading to add a party may serve the party to be added by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. Service by first-class mail or overnight mail service would be accomplished on the date of mailing. Service by any other means would be accomplished on the date of delivery. FINRA would permit the party to be added to file a response with the Director and serve the response on all other parties by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. Since the arbitrators may ultimately decline the motion to add a new party, FINRA believes it makes sense to allow service by methods other than the Party Portal while the arbitrators consider the motion.[26]

12310—Answering Amended Claims

FINRA Rule 12310 describes how parties answer amended claims. Rule 12310(b) provides that if a claim is amended after it has been answered, but before a panel has been appointed, the respondent has 20 days from "the time the amended claim is served" to serve an amended answer. Since parties would be serving each other through the Party Portal, FINRA is proposing to amend Rule 12310(b) to delete the phrase "the time the amended claim is served" to provide instead that the respondent has 20 days from "receipt of the amended claim" to serve an amended answer. FINRA uses time of receipt in the rules relating to parties' time to respond to answers, among other matters, and believes consistent language would add clarity to the rule.[27]

FINRA is also proposing to amend Rule 12310(d) relating to serving an amended answer to delete the reference to "directly" serving each other party, and providing copies of the pleading for the arbitrators.

Finally, FINRA is proposing to add clarity to Rule 12310(e) concerning when a new party's answer is due, by stating that the new party's "time to" answer is governed by Rules 12303 or Rule 12306 (which include a 45 day period for answers).

12400—Neutral List Selection System and Arbitrator Rosters

FINRA is proposing to amend FINRA Rule 12400(b) relating to its arbitrator rosters and Rule 12400(c) concerning eligibility for chairperson roster to update cross-references and replace bullets with numbers.

12402—Cases With One Arbitrator and 12403—Cases With Three Arbitrators

FINRA is proposing to amend FINRA Rules 12402(d)(3) and 12403(c)(3) concerning striking and ranking arbitrators to provide that parties must complete arbitrator ranking through the Party Portal unless a party is a *pro se* customer who opted out of using the Party Portal. The rule would list the approved methods for *pro se* customers to return ranked lists. FINRA is also proposing to amend to Rule 12402(e) to replace bullets with numbers.[28]

12404—Additional Parties

FINRA Rule 12404 describes procedures for newly added parties to rank and strike arbitrators. FINRA is proposing to amend Rule 12404(a) to reflect that since parties would complete the ranking and striking process in the Party Portal, they would no longer "return" lists to the Director. FINRA would also amend this provision to correct a typographical error by adding "(s)" to the term "list" in the paragraph's last sentence because in cases with three arbitrators, parties return three lists of arbitrators, not just one.

Rule 12404(b) explains that after ranked arbitrator lists are due to the Director, parties may not amend pleadings to add new parties until FINRA appoints a panel and the panel grants a motion to add a new party. Motions to add a party must be served on all parties. FINRA is proposing to amend Rule 12404(b) to provide that the party seeking to amend the pleading must serve the party to be added by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. Service by first-class mail or overnight mail service would be accomplished on the date of mailing. Service by any other means would be accomplished on the date of delivery. FINRA would permit the party to be added to file a response with the Director and serve the response on all other parties by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. Since the arbitrators may ultimately decline the motion to add a new party, FINRA believes it makes sense to allow service by methods other than the Party Portal while the arbitrators consider the motion.

12500—Initial Prehearing Conference

FINRA Rule 12500(c) describes the subject matter of the initial prehearing conference and provides that parties may forgo the conference if they provide certain information (as described in accompanying bullets) in writing to the Director. FINRA is proposing to amend the rule to delete the requirement that parties provide copies of the written submission for the arbitrators. FINRA is also proposing to replace the bullets with numbers.

12502—Recording Prehearing Conferences and 12606—Record of Proceedings

FINRA Rule 12502 provides that FINRA does not record prehearing conferences unless the panel orders a recording, and FINRA Rule 12606(a) specifies that FINRA records hearings. Both rules provide that the Director will provide copies of a tape, digital, or other recording to parties for a nominal fee. FINRA is proposing to amend the rules to delete the reference to a fee because FINRA currently provides parties with copies of recordings free of charge. Rule

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[26] FINRA Rule 13309(c) in the Industry Code contains an erroneous cross-reference to Rule 13404(c). FINRA is proposing to amend Rule 13309(c) to refer to Rule 13404(d) which relates to the time frame when ranked lists are due.

[27] *See* FINRA Rules 12303 (Answering the Statement of Claim), 12304 (Answering Counterclaims), 12305 (Answering Cross Claims), and 12306 (Answering Third Party Claims).

[28] The Industry Code rules relating to arbitrator appointment, while substantially similar to the Customer Code rules, are not identical to the Customer Code and are numbered differently. FINRA is proposing to amend FINRA Rule 13404(d) concerning striking and ranking arbitrators, to provide that parties must complete arbitrator ranking through the Party Portal. FINRA is proposing to amend FINRA Rule 13406 relating to appointment of arbitrators to update a cross-reference and to replace bullets with letters. FINRA is also proposing to amend FINRA Rule 13411 concerning replacing arbitrators to update a cross-reference.

12606(a) also provides that the panel may order parties to provide a transcription of the recording. FINRA is proposing to amend Rule 12606(a) to clarify that if the arbitrators order the parties to provide a transcript, the parties must provide copies for the arbitrators and must file the transcript with the Director and serve it on the other parties. Rule 12606(b) provides that parties may make stenographic records of a hearing. FINRA is proposing to amend Rule 12606(b) to clarify that if the stenographic record is the official record of the proceeding, the parties must provide copies for the arbitrators and must file the transcript with the Director and serve it on the other parties.

Some FINRA arbitrators have indicated that they prefer to review long documents in hard copy. Therefore, to ensure efficiency in case administration, FINRA would continue to require parties to provide copies of transcripts for the arbitrators.

12503—Motions

FINRA Rule 12503 specifies how parties make motions at the forum. Under the proposed rule change, parties would be required to file motions with the Director and serve other parties through the Party Portal. Therefore, FINRA is proposing to amend Rule 12503(a)(2) to delete the requirement that parties serve motions on each other directly, at the same time and in the same manner, and provide FINRA with copies for each arbitrator. FINRA would make the same deletions to Rule 12503(b) relating to responding to motions and Rule 12503(c) concerning replying to responses to motions.

FINRA is also proposing to amend Rule 12503(a)(4) to delete the text specifying how parties make motions to amend a pleading to add a party to a case, because these motions would be addressed in Rule 12309(c) (discussed above). FINRA would add a cross-reference to Rule 12309(c).

12506—Document Production Lists

FINRA Rule 12506(a) provides that when the Director serves respondents with the statement of claim, the Director notifies parties of the location of the FINRA Discovery Guide and Document Production Lists on FINRA's Web site. In view of the Party Portal, FINRA is proposing to amend the rule to delete the reference to "when the Director serves the statement of claim." The rule would continue to state that the Director will notify parties of the location of the FINRA Discovery Guide and Document Production Lists on FINRA's Web site.

FINRA Rule 12506(b) specifies, among other matters, the time for parties to respond to the Document Production Lists. FINRA wants parties to file their explanations about why they are not timely producing documents and why they are objecting to production. FINRA believes that having this correspondence in the Party Portal would be efficient for FINRA staff and the parties. However, FINRA does not want the parties to file with the Director the documents and information that they produce during discovery. Therefore, FINRA is proposing to amend Rule 12506(b) to specify that parties must serve each other with documents produced pursuant to the rule by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile as provided in Rule 12300(a)(3). The rule would also provide that parties are required to file any written responses relating to discovery, such as objections to producing items in the Document Production Lists, with the Director through the Party Portal.

FINRA is also proposing to amend to Rule 12506(b) to replace bullets with letters.[29]

12507—Other Discovery Requests

FINRA Rule 12507(a) provides that parties may request additional documents from a party by serving the party directly with a written request. The rule requires the requesting party to serve copies of the request on all other parties at the same time. Since parties would be serving each other through the Party Portal, FINRA is proposing to amend the rule to delete the requirement for direct service in Rule 12507(a)(1) and the requirement to serve all other parties at the same time in Rule 12507(a)(2).

FINRA Rule 12507(b) specifies how parties may respond to an additional discovery request. The parties can: (1) Produce the documents or information (Rule 12507(b)(1)(A)); (2) identify specific documents that will not be produced within the required time and state when the documents will be produced (Rule 12507(b)(1)(B)); or (3) object to the request (Rule 12507(b)(1)(C)). As explained earlier, FINRA does not want parties to file with the Director the documents and information that they produce during discovery. Therefore, FINRA is proposing to amend Rule 12507(b)(1)(A) to specify that if a party produces documents or information pursuant to a request, the party must serve all other parties with copies of the requested documents or information by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile.

However, FINRA wants to receive party explanations about why they are not timely producing documents and why they are objecting to production. Therefore, FINRA would amend Rule 12507(b)(1)(B) concerning non-production to provide that a party must file a response with the Director and serve it on all other parties (through the Party Portal). FINRA would also amend Rule 12507(b)(1)(C) concerning objections to provide that a party must file the objection with the Director and serve it on all other parties (through the Party Portal).

Finally, FINRA is proposing to replace the bullets in Rule 12507 with numbers.

12508—Objecting to Discovery; Waiver of Objection

FINRA Rule 12508 addresses party objections to producing documents and information during discovery. To reflect how parties will be serving each other through the Party Portal, FINRA is proposing to amend the rule to delete the requirement that parties serve their objections on each other at the same time and in the same manner. Since FINRA wants to receive party explanations about why they are objecting to production, FINRA is proposing to amend the rule to delete the statement that objections should not be filed with the Director.

12512—Subpoenas

FINRA Rule 12512 specifies that arbitrators may issue subpoenas to parties and non-parties for the production of documents and evidence, and outlines how FINRA handles motions for subpoenas at the forum. To reflect how motion practice would operate through the Party Portal, FINRA is proposing to amend Rule 12512(b) to delete the requirements that parties provide copies of the subpoena for the arbitrator, and serve the motion on each other at the same time and in the same manner. FINRA would make the same amendment to Rule 12512(c) concerning party objections to subpoenas.

Rule 12512(d) addresses service of an executed subpoena. FINRA is proposing to amend the rule to delete the requirement that parties serve the subpoena on each other at the same time and in the same manner. In addition, since non-parties do not have access to the Party Portal, FINRA would amend the rule to specify that when an arbitrator issues a subpoena to a non-party, the party must serve the subpoena on the non-party by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile.

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[29] The FINRA Discovery Guide and related Document Production Lists apply only to customer arbitrations. Therefore, the Industry Code does not contain Document Production Lists. The discovery rules in the Industry Code that are substantially similar to Rule 12507 in the Customer Code are Rule 13506 (Discovery Requests) and Rule 13507 (Responding to Discovery Requests). The proposed amendments to Rules 13506 and 13507 are substantively identical to those in Rule 12507.

Rule 12512(e) provides for a non-party's objection to a subpoena. If a non-party receiving a subpoena objects to the scope or propriety of the subpoena, FINRA permits the non-party to file written objections with the Director. Under the rule, the party that requested the subpoena may respond to the objection. FINRA is proposing to amend the rule to provide that the non-party may file the objection by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile, and that the party must serve the response on the non-party and file proof of service with the Director.

Rule 12512(f) outlines procedures for parties to follow when they receive subpoenaed documents from non-parties. Specifically, the rule provides that any party that receives documents in response to a subpoena served on a non-party has five days to provide notice of the receipt to the other parties. Other parties to the case may request copies of the documents, and the party in receipt of the documents must provide them within 10 calendar days of receipt of the request. FINRA is proposing to amend the rule to specify that a party that receives documents from a non-party in response to a subpoena must serve the other parties with notice that the party received the documents. Other parties to the case may request copies of the subpoenaed documents. Since FINRA does not want the parties to submit the documents to the Director, FINRA would amend the rule to provide that the party must serve the documents on the other parties by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. The rule would also expressly prohibit parties from filing the documents with the Director.

12513—Authority To Direct Appearances of Associated Person Witnesses and Production of Documents Without Subpoenas

FINRA Rule 12513 authorizes arbitrators to order the appearance of firm employees and associated persons, and the production of documents from firms and their employees and associated persons without issuing a subpoena. FINRA is proposing to amend several provisions in the rule to reflect how FINRA would handle a party's motion for an arbitrator order using the Party Portal.

FINRA is proposing to amend Rule 12513(b) concerning filing the motion to delete the requirement that a party provide a copy for the arbitrator and that the party serve the motion on all other parties at the same time and in same manner as on the Director. FINRA is proposing to make the same changes to Rule 12513(c) relating to an opposing party's objection to the motion, and to Rule 12513(d) relating to party service of an order.

In addition, since FINRA will not invite a non-party to use the Party Portal, FINRA is proposing to amend Rule 12513(d) to provide that if a party obtains an arbitrator's order for a non-party's production, then the party must serve the order on the non-party. FINRA would also amend Rule 12513(e) to provide that if the non-party files an objection to the arbitrator's order, and the party requesting the order wants to file a response to the objection, then the party must serve the response on the non-party and provide the Director with proof of service. Finally, FINRA is proposing to amend Rule 12513(f) to provide that any party receiving documents from a non-party must serve notice on all other parties. If any other party requests copies of the documents, the requesting party must serve them by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. The amendments would also specify that parties must not file with the Director the documents produced pursuant to the order.

12514—Prehearing Exchange of Documents and Witness Lists, and Explained Decision Requests

FINRA Rule 12514 sets forth procedures for exchanging documents and witness lists prior to the first scheduled hearing date and for making joint party requests for an explained decision. FINRA is proposing to amend Rule 12514(b) to delete the requirement that parties file their witness lists with the Director at the same time as they notify other parties and provide the Director with enough copies for the arbitrators. Instead, Rule 12514(b) would require that all parties file their witness lists only with the Director. FINRA would also amend Rule 12514(d) to provide that parties must file with the Director requests for an explained decision as opposed to submitting them to the arbitrators.

12701—Settlement

FINRA Rule 12701 requires parties to notify the Director of settlements. FINRA is proposing to amend Rule 12701(a) to reflect use of the Party Portal by replacing "notify" with "file notice with" the Director.

12800—Simplified Arbitration

FINRA Rule 12800 provides special procedures for the administration of disputes involving $50,000 or less, including procedures for parties to request documents and other information from each other. FINRA is proposing to amend Rule 12800(d) to provide that parties receiving the request must produce the requested documents or information to all other parties by serving the requested documents or information by first-class mail, overnight mail service, overnight delivery service, hand delivery, email or facsimile. The proposed rule would specify that parties must not file the documents with the Director.

12801—Default Proceedings

FINRA Rule 12801 specifies procedures for initiating default proceedings against certain respondents (*e.g.,* terminated members). Since parties would be using the Party Portal to file notice with the Director and serve other parties with their request to initiate a default proceeding, FINRA is proposing to amend Rule 12801(b) to delete the requirements for parties to notify the Director in writing, and send a copy of the notification to other parties at the same time and in the same manner. FINRA is also proposing to amend Rule 12801(a) to replace bullets with numbers.

12901—Member Surcharge

FINRA Rule 12901 provides that FINRA will assess surcharges against members under specified circumstances. Rule 12901(a)(3) states that if the claim is filed by a member, the surcharge is due when the claim is filed. If the claim is filed against a member, or against an associated person employed by a member at the time of the events giving rise to the dispute, the surcharge is due when the claim is served. FINRA is proposing to amend the rule to provide that if a claim is filed against a member or associated person, the surcharge is due when the Director serves the Claim Notification Letter or the initial statement of claim. FINRA is also proposing to amend Rule 12901(a) and 12901(b) to replace bullets with letters.

12094—Awards

FINRA Rule 12904 concerns arbitrator awards and includes, among other matters, procedures for the Director to serve awards on parties. The rule provides that the Director serves an award using any method available and convenient to the parties and the Director, and that is reasonably expected to cause the award to be delivered to all parties, or their representative, on the same day. Under the rule, the Director may serve an award by first class, registered or certified mail, hand delivery, and facsimile or other electronic transmission. Since the Director will serve the award through the Party Portal in most instances, FINRA is proposing to amend Rule 12904(c) to provide only that the Director will serve the award on each party, or their representative.

Industry Code Specific Amendments

As explained earlier, while the discussion details the proposed amendments to the FINRA rules in the Customer Code, FINRA is also proposing to make substantively similar amendments to the Industry Code. In addition to the amendments discussed, FINRA is proposing to amend rules in the Industry Code that are unique to intra-industry disputes.

13802—Statutory Employment Discrimination Claims

FINRA is proposing to amend FINRA Rule 13802(a) relating to statutory employment discrimination claims to update a cross-reference concerning the definition of statutory employment discrimination. FINRA would also amend Rule 13802(c) to replace bullets with numbers.

13804—Temporary Injunctive Orders; Requests for Permanent Injunctive Relief

The Industry Code also has special procedures for handling temporary injunctions with respect to an industry or clearing dispute. FINRA is proposing to amend FINRA Rule 13804(a) to provide that parties seeking temporary injunctive relief from a court must file with the Director a statement of claim requesting permanent injunctive and all other relief with respect to the same dispute through the Party Portal, and must serve the statement of claim requesting permanent injunctive and all other relief on all other parties by overnight delivery service, hand delivery, email or facsimile. The rule would require parties to serve all parties at the same time and in the same manner, unless the parties agree otherwise.

Cases involving injunctive relief operate on an accelerated time schedule. It takes FINRA staff some time to review an initial submission and invite respondent parties to use the Party Portal. In view of the need to expedite these matters, FINRA believes that parties should serve each other outside of the Party Portal until FINRA establishes the identities of all relevant parties and their representatives, and invites them to access the Party Portal.

Mediation Code

Under the proposed rule change, FINRA would permit parties to a mediation proceeding to use the Party Portal on a voluntary basis. FINRA is proposing to amend the Mediation Code to reflect use of the Party Portal.

14100—Definitions

FINRA is proposing to amend FINRA Rule 14100 to define "Arbitrator and Mediator Portal" and "Party Portal." The definitions would be identical to the definitions in the Codes. FINRA would re-letter the definitions because of the new additions.

14109—Mediation Ground Rules

FINRA also is proposing to amend FINRA Rule 14109 to provide that the parties may agree to use the Party Portal to submit all documents and other communications to each other, to retrieve all documents and other communications, and view mediation case information.

Effective Date of Proposed Rule Change

As noted in Item 2 of the filing, if the Commission approves the proposed rule change, FINRA will announce the effective date of the proposed rule change in a *Regulatory Notice* to be published no later than 60 days following Commission approval. The effective date will be no later than 90 days following publication of the *Regulatory Notice* announcing Commission approval.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[30] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. The proposed rule change is consistent with section 15A(b)(6) because it would enhance efficiencies for forum users and would expedite case administration by FINRA.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Most parties are currently using the Party Portal voluntarily to file claims and retrieve documents. Thus, under the proposal, the impact on forum users would be minimal.

By requiring parties to file their claims online, the proposal would expedite the case intake process and would ensure better data accuracy. Prior to implementation of the proposal, however, FINRA would be required to: (1) Update staff procedures to ensure consistency with the new rules; (2) provide instructions for customers in plain English on how to access the Party Portal and use its features; and (3) make some technological changes to various computer systems to incorporate the functions under the proposal that are not currently available to parties.

Economic Impact Assessment

The proposal is intended to introduce an enhanced technology platform into the dispute resolution process to create efficiencies in collecting, preserving and distributing documents, which would expedite case administration and add new features for parties. Parties that would be required to use the Party Portal would benefit from these efficiencies; *pro se* customers would be exempted (provided they opt out of using the Party Portal).

When FINRA activated the Party Portal, FINRA initially limited the number of firms permitted to use the Party Portal to file and receive case documents, among other things, as a proof of concept. Customers initiating claims against one of the invited firms were given the option of using the Party Portal to administer their case. Soon after the parties began using the Party Portal, and learned of the benefits and cost savings realized through the technology, customers and firms indicated a desire to use the Party Portal. As of May 11, 2016, there are 18 firms that use the Party Portal to receive service of the statement of claim and to administer their cases electronically in every instance. In addition, in most of the remaining cases administered at the forum, firms and associated persons are opting to use the Party Portal for case administration after they receive the statement of claim. As of July 20, 2015, FINRA opened the Party Portal to accept all parties in all new cases that wish to use it on a voluntary basis.

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[30] 15 U.S.C. 78o–3(b)(6).

As of May 11, 2016, FINRA has processed 4,932 cases through the Party Portal. FINRA has invited 13,562 parties (customers, and firms and associated persons) to register and use the Party Portal. Of the 13,562 parties, 76 percent of customers, including *pro se* customers, have been using the Party Portal voluntarily and 82 percent of firms and associated persons, which includes firm representatives, have been using the Party Portal voluntarily (78 percent in total). FINRA has processed over 16,000 party documents through the Party Portal, including answers, motions, and correspondence. Over 83 percent of parties have used the Party Portal to view their case-related correspondence.

Based on the parties' experience to date with the Party Portal, along with the feedback provided from current users of this platform, FINRA believes those parties required to use the Party Portal would realize the anticipated benefits of the proposal. Further, the adoption of the Party Portal by parties on a voluntary basis suggests that they see benefit from its availability and use.

Under the proposal, most parties would no longer be required to send paper copies of pleadings or other documents to FINRA. Thus, these parties would experience cost savings related to the preparation and mailing of such submissions. Further, parties would be able to serve each other immediately through the Party Portal, rather than through other means, which, under current rules, may involve mailing hard copies to all parties at the same time. FINRA acknowledges that those customers or firms that have not used the Party Portal previously may incur some time and effort to learn the Party Portal system, but the technology requirements (*i.e.*, a computer with Internet access) will be minimal, and, therefore, should not impede a party's access to the dispute resolution process.

FINRA staff understands that requiring *pro se* customers to use the Party Portal might impose a higher burden on these individuals given their potentially limited access to and experience with the required technology. Thus, staff is proposing to allow *pro se* customers to opt out of using the Party Portal. However, *pro se* customers may choose to use the Party Portal, which would allow them to benefit equally from the efficiencies that the Party Portal is anticipated to create. Staff notes that, as of May 11, 2016, 3,599 *pro se* customers or customer representatives have been invited to register, with 4,711 agreeing to do so (a 76 percent registration rate).

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2016–029 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–029. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–029 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19580 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78546; File No. SR–NYSEARCA–2016–109]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing of Proposed Rule Change Amending Rule 6.91(b) To Provide for the Rejection of Certain Electronic Complex Orders

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2016, NYSE Arca, Inc. (the "Exchange" or "NYSE Arca") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 6.91(b) to provide for the rejection of certain Electronic Complex Orders. The proposed rule change is available on the Exchange's Web site at

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[31] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

www.nyse.com, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 6.91(b) to provide for the rejection of certain Electronic Complex Orders ("ECOs").[3] Specifically, the Exchange proposes to reject certain ECOs that may undermine the effectiveness of risk limitation mechanisms designed to protect Market Makers.

The Exchange requires a Market Maker to utilize its risk limitation mechanisms, which automatically remove a Market Maker's quotes in all series of an options class when certain parameter settings are triggered.[4] This functionality is designed to mitigate the risk of multiple executions on a Market Maker's quotes occurring simultaneously across multiple series and multiple option classes. Pursuant to Rule 6.40, the Exchange establishes a time period during which the System calculates: (1) The number of trades executed by the Market Maker in a specified options class; (2) the volume of contracts traded by the Market Maker in a specified options class; or (3) the percentage of the Market Maker's quoted size in the specified class that has been executed (the "risk settings").[5] When a Market Maker has breached its risk settings (*i.e.*, has traded more than the contract or volume limit or cumulative percentage limit of a class during the specified measurement interval), the System will cancel all of the Market Maker's quotes in that class until the Market Maker notifies the Exchange it will resume submitting quotes.[6] The purpose of the risk settings, therefore, is to allow Market Makers to provide liquidity across potentially thousands of options series without being at risk of executing the full cumulative size of all such quotes before being given adequate opportunity to adjust their quotes.

An incoming ECO may execute against quotes or individual orders comprising the Complex Order (the "leg markets") or against ECOs resting in the Consolidated Book.[7] An ECO trading against the leg markets is commonly referred to as "legging out." Current Rule 6.91(a)(2)(ii) provides that an incoming ECO will execute first with the leg markets, ahead of resting ECOs at the same price (*i.e.*, the same total net debit or credit), provided the leg markets can execute the ECO in full or in a permissible ratio.

The execution of certain ECOs against the leg markets can be problematic because ECOs that leg out may execute before triggering a Market Maker's risk settings. Specifically, because the execution of each leg of an ECO is contingent on the execution of the other legs, the execution of all individual leg markets is processed as a single transaction, not as a series of individual transactions. Thus, while the risk settings allow a Market Maker to manage the risks associated with providing liquidity across multiple series of an options class, the settings do not adequately provide this risk protection because the legs of an ECO execute in a single transaction package before processing any subsequent messages. The practical result is that because all legs of an ECO execute before a Market Marker has an opportunity to react, such ECO executions are essentially able to bypass the Market Maker's risk settings.

Of particular concern to the Exchange are ECOs where two or more legs are buying (selling) calls (puts), which are commonly referred to as "directional complex orders." Such directional complex orders are typically geared towards an aggressive directional capture of volatility. Specifically, through a combination of buying or selling of multiple option legs at once, a market participant using one of these strategies is aggressively buying or selling volatility. By contrast, other types of complex strategies are designed to gain exposure to a particular option class' movement.[8] The Exchange has seen a recent increase in the use of directional complex orders as a way to trade against multiple series on the same side of the market without triggering Market Maker risk settings. If the same legs were sent as individual orders, rather than as components of a directional complex order, Market Maker risk settings may have been triggered.[9] The Exchange is concerned that the use of directional complex orders is undermining the important purpose of the Market Makers risk settings, which the Exchange requires Market Makers to use for all quotes.

To address the potential for directional ECOs to undermine the purposes of the Market Maker risk settings, the Exchange proposes to amend Rule 6.91(b)(4). Specifically, the Exchange proposes to reject an ECO if:

(i) Composed of two legs that are (a) both buy orders or both sell orders, and (b) both legs are calls or both legs are puts; *or*

(ii) composed of three or more legs and (a) all legs are buy orders; or (b) all legs are sell orders.[10]

The proposed rule change would not impact the processing of ECOs trading against other ECOs or the priority and allocation of ECOs. The following examples illustrate the types of ECOs that would be rejected under proposed Rule 6.91(b):

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[3] Rule 6.62(e) defines a Complex Order as any order involving the simultaneous purchase and/or sale of two or more different option series in the same underlying security, for the same account, in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purpose of executing [sic] particular investment strategy. Per Rule 6.91, an ECO is a Complex Order that has been entered into the NYSE Amex Options System ("System") for execution. *See* Rule 6.91 (preamble).

[4] *See* Rule 6.40(b)(3), (c)(3) and (d)(3). Market Makers are required to utilize one of the three risk settings for their quotes. *See* Commentary .04 to Rule 6.40. Market Makers and OTP Holders may utilize the risk limitation mechanisms for certain orders, but they are not required to do so. *See, e.g.*, Rule 6.40(b)(1), (2); (c)(1), (c)(2).

[5] *See* Rule 6.40(b)(3), (c)(3) and (d)(3). Market Makers are required to utilize one of the three risk settings for its quotes. *See* Commentary .04 to Rule 6.40.

[6] *See* Commentary .01 to Rule 6.40 (requiring that a Market Maker request that it be re-enabled after a breach of its risk settings).

[7] *See* Rule 6.91(a)(2)(ii).

[8] The Exchange notes that the majority of ECOs are calendar and vertical spreads, butterflies and straddles, which are designed to hedge the potential move of the underlying security or to capture premium from an anticipated market event.

[9] For example, if individual orders to buy 10 contracts for the Jan 30 call, Jan 35 call and Jan 40 call are entered, each is processed as it is received and the Market Maker risk settings are calculated following the execution of each 10-contract order. Thus, if either the first order or the second order trigger a Market Maker's risk settings, the System would cancel all of the Market Maker's quotes in that class until the Market Maker notifies the Exchange it will resume submitting quotes (*see* Commentary .01 to Rule 6.40). However, if an ECO to buy all three of these options with a quantity of 10 contracts is entered and is executed against the leg markets, the Market Maker risk settings for quotes in the leg market are calculated only after the execution of all 30 contracts (the sum of the three legs of 10 contracts each) because the execution of all individual leg markets is processed as a single transaction, not as a series of individual transactions.

[10] *See* proposed Rule 6.91(b). The Exchange also proposes to delete the words "Types of" in the first paragraph because sub-paragraphs (1)–(4) of paragraph (d) do not describe the "types of" ECOs, but rather describe the requirements for such orders.

Example #1: Illustrating Proposed Rule 6.91(b)(4)(i)

- Buy Call 1, Buy Call 2
- Sell Call 1, Sell Call 2
- Buy Put 1, Buy Put 2
- Sell Put 1, Sell Put 2

Example #2: Illustrating Proposed Rule 6.91(b)(4)(ii)

- Buy Call 1, Buy Call 2, Buy Put 1
- Buy Put 1, Buy Put 2, Buy Put 3
- Buy Call 1, Buy Call 2, Buy Call 3
- Buy Put 1, Buy Put 2, Buy Call 3
- Sell Put 1, Sell Put 2, Sell Call 1

As proposed, the specified directional complex orders would be automatically rejected. Market participants would continue to be able to enter each leg of such complex orders as separate orders. The Exchange believes that the potential risk of these types of directional complex orders undermining the effectiveness of Market Maker risk settings outweighs any potential benefit to OTP Holders or OTP Firms submitting such orders.

Finally, the Exchange notes that both the Chicago Board Options Exchange, Inc. ("CBOE") and International Securities Exchange, LLC ("ISE") have recently received Commission approval to revise their rules governing complex orders to implement functionality designed to prevent complex orders from effectively bypassing market maker risk parameters.[11]

Implementation

The Exchange will announce the implementation date of the proposed rule change by Trader Update.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Securities Exchange Act of 1934 (the "Act"),[12] in general, and furthers the objectives of section 6(b)(5) of the Act,[13] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The proposed rule change would prevent fraudulent and manipulative acts and practices and would remove impediments to and perfect the mechanism of a free and open market because it would enable the Exchange to reject (and therefore prevent the execution of) certain directional complex order strategies that may undermine important Market Maker risk settings, which are required for all Market Maker quotes. The Exchange believes that rejecting the specified directional orders outright provides clarity as to the disposition of ECOs submitted by market participants and assures that the Market Maker risk settings will operate as intended. The Exchange notes that other markets have amended their rules to prevent directional complex orders from undermining market maker risk settings and do not allow such orders to leg out.[14] Because of the non-traditional nature of these directional complex orders, the Exchange believes it unlikely that they would execute against complex interest. Accordingly, the Exchange believes rejecting the orders outright (as opposed to simply preventing them from legging out) would have the same practical impact for the order-sending firms and would be the most effective and transparent means of handling these orders. Furthermore, the Exchange believes that the risk of the specified directional complex orders undermining the efficacy of Market Maker risk settings outweighs any potential benefit to OTP Holders or OTP Firms submitting such orders packaged as ECOs. The Exchange notes that market participants would continue to be able to enter each leg of such complex orders as separate orders. The Exchange also believes this proposal would protect investors and the public interest because it would help eliminate a degree of unnecessary risk borne by Market Makers when fulfilling their quoting obligations to the markets and would encourage them to contribute liquidity on the Exchange. The Exchange believes the strengthened risk settings would encourage Market Makers to provide tighter and deeper markets, to the benefit of all market participants.

B. Self-Regulatory Organization's Statement on Burden on Competition

The proposed rule change would prevent fraudulent and manipulative acts and practices and would remove impediments to and perfect the mechanism of a free and open market because, by rejecting (and therefore preventing the execution of) certain directional complex order strategies that may undermine important Market Maker risk settings, which are required for all Market Maker quotes. The Exchange believes that rejecting the specified directional orders outright provides clarity as to the disposition of ECOs submitted by market participants and assures that the Market Maker risk settings will operate as intended. The Exchange notes that other markets have amended their rules to prevent directional complex orders from undermining market maker risk settings and do not allow such orders to leg out.[15] Because of the non-traditional nature of these directional complex orders, the Exchange believes it unlikely that they would execute against complex interest. Accordingly, the Exchange believes rejecting the orders outright (as opposed to simply preventing them from legging out) would have the same practical impact for the order-sending firms and would be the most effective and transparent means of handling these orders. Furthermore, the Exchange believes that the risk of the specified directional complex orders undermining the efficacy of Market Maker risk settings outweighs any potential benefit to OTP Holders or OTP Firms submitting such orders packaged as ECOs. The Exchange notes that market participants would continue to be able to enter each leg of such complex orders as separate orders. The Exchange also believes this proposal would protect investors and the public interest because it would help eliminate a degree of unnecessary risk borne by Market Makers when fulfilling their quoting obligations to the markets and would encourage them to contribute liquidity on the Exchange. The Exchange believes the strengthened risk settings would encourage Market Makers to provide tighter and deeper markets, to the benefit of all market participants.

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[11] *See* Securities Exchange Act Release Nos. 73023 (September 9, 2014) 79 FR 55033 (September 15, 2014) (SR–ISE–2014–10) and 72986 (September 4, 2014) 79 FR 53798 (September 10, 2014) (SR–CBOE–2014–017) (Approval Order). *See also* Securities Exchange Act Release Nos. 76106 (October 8, 2015) 80 FR 62125 (October 15, 2015) (SR–CBOE–2014–081); 77297 (March 4, 2016), 81 FR 12764 (March 10, 2016) (SR–CBOE–2016–014) (further amending the complex order rule, as modified by the Approval Order, to limit a potential source of unintended market maker risk). The Exchange acknowledges that, unlike this proposal, CBOE and ISE do not reject the offending ECOs outright.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

[14] See supra n. 11.

[15] See supra n. 11.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange believes that the proposal qualifies for accelerated effectiveness in accordance with section 19(b)(2) of the Act. The Exchange believes that there is good cause for the Commission to accelerate effectiveness because the proposed rule change is consistent with the rules of at least two competing options markets, which have amended their rules to prevent directional complex orders from undermining market maker risk settings and do not allow such orders to leg out.[16] The Exchange would like to similarly enhance the protection it provides to Market Makers. Because of the non-traditional nature of these directional complex orders, the Exchange believes it unlikely that they would execute against complex interest. Accordingly, the Exchange believes rejecting the orders outright (as opposed to simply preventing them from legging out) would have the same practical impact for the order-sending firms and would be the most effective and transparent means of handling these orders. Thus, accelerated approval of this proposal would enable the Exchange to implement the rule change without delay, thereby strengthening market maker risk settings and enhancing the competitiveness of the Exchange.

In addition, the Exchange believes that the proposed rejection of the specified directional complex orders would prevent such orders from executing before triggering (and thus, bypassing) the Market Maker risk settings. The Exchange believes that the potential risk of these types of directional complex orders undermining the effectiveness of Market Maker risk settings outweighs any potential benefit to OTP Holders or OTP Firms submitting such orders. Market participants would continue to be able to enter each leg of such complex orders as separate orders. Thus, the Exchange believes good cause exists to accelerate effectiveness of this proposal because it would help eliminate a degree of unnecessary risk borne by Market Makers when fulfilling their quoting obligations to the markets, which would in turn benefit all market participants because Market Makers would be encouraged to provide tighter and deeper markets.

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEARCA–2016–109 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEARCA–2016–109. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEARCA–2016–109 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19577 Filed 8–16–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78554; File No. SR–CBOE–2016–059]

Self-Regulatory Organizations; Chicago Board Options Exchange, Incorporated; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Relating to COPS

August 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 1, 2016, Chicago Board Options Exchange, Incorporated (the "Exchange" or "CBOE") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The purpose of the proposed rule change is to re-implement the contributor compensation structure of the Exchange's Customized Option Pricing Service ("COPS"),[3] specifically, the COPS data revenue-sharing plan. The Exchange is not proposing to change the fees for COPS data.

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[16] See supra n. 11.

[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release Nos. 34–67813 (September 10, 2012), 77 FR 56903 (September 14, 2012) (SR–CBOE–2012–083); 34–67928 (September 26, 2012), 77 FR 60161 (October 2, 2012) (SR–CBOE–2012–090); 34–70705 (October 17, 2013), 78 FR 63265 (October 23, 2013) (SR–CBOE–2013–097); 34–70845 (November 12, 2013),

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of the proposed rule change is to re-implement the contributor compensation structure of the Exchange's COPS,[4] specifically, the COPS data revenue-sharing plan. The Exchange is not proposing to change the fees for COPS data.

Background

COPS provides market participants with an "end-of-day" [5] file and "historical" [6] files of valuations for Flexible Exchange ("FLEX") [7] options and certain over-the-counter ("OTC") options (collectively, "COPS Data"). Market Data Express, LLC ("MDX"), an affiliate of CBOE, offers COPS Data for sale to all market participants. COPS Data is available to "Subscribers" for internal use and internal distribution only, and to "Customers" who, pursuant to a written vendor agreement between MDX and a Customer, may distribute the COPS Data externally (*i.e.*, act as a vendor) and/or use and distribute the COPS Data internally.

COPS Data consists of indicative [8] values for four categories of "customized" options. The first category of options is all open series of FLEX options listed on any exchange that offers FLEX options for trading.[9] The second category is OTC options that have the same degree of customization as FLEX options. The third category includes options with strike prices expressed in percentage terms. Values for such options are expressed in percentage terms and are theoretical values.[10] The fourth category includes "exotic" options.[11]

The Exchange uses values produced by CBOE Trading Permit Holders ("TPHs") to produce COPS Data. Participating CBOE TPHs submit values to MDX on options series specified by MDX on a daily basis. These values are generated by the TPHs' internal pricing models. The valuations that MDX ultimately publishes are an average of multiple contributions of values from participating CBOE TPHs. For each value provided by MDX through COPS, MDX includes a corresponding indication of the number of TPH contributors that factored into that value.

CBOE TPHs that meet the following objective qualification criteria are allowed to contribute values to MDX for purposes of producing COPS Data. Interested CBOE TPHs must be approved by the Exchange, have the ability to provide valuations to MDX in a timely manner each day after the close of trading, and sign a services agreement with CBOE. Interested CBOE TPHs must also have the ability to provide both indicative and implied volatility valuations on several different types of options, including (i) options on all open FLEX series traded on any exchange that offers FLEX options for trading, (ii) options on any potential new FLEX options series, (iii) OTC options that have the same degree of customization as FLEX options, (iv) customized options where the strike price is expressed in percentage terms (the valuations provided to MDX must also be expressed in percentage terms), and (v) exotic options. In addition, interested CBOE TPHs must participate in a testing phase with MDX. The values submitted by a TPH during the testing phase and in live production must meet MDX's quality control standards designed to ensure the integrity and accuracy of COPS Data. MDX has implemented procedures including monthly performance reviews to help ensure the integrity and accuracy of COPS Data.

To help ensure that MDX receives numerous values from multiple TPHs on a consistent basis, MDX shares revenue from the sale of COPS Data with participating CBOE TPHs.[12] The amount of revenue that MDX shares with participating TPHs is a percentage of the total revenue received by MDX from the sale of COPS Data. The revenue sharing is based on the following table:

Number of participating TPHs	Total revenue share (percent)	Revenue share per TPH
3	21	7%.
4	24	6%.
5 or more	30	30% divided by the number of participating TPHs.

If only three TPHs participate, MDX shares 21% of total revenue with each TPH receiving a 7% share. If four TPHs participate, MDX shares 24% of total revenue with each TPH receiving a 6% share. If five or more TPHs participate, MDX shares 30% of total revenue divided equally among the TPHs.

In July 2014, the Exchange submitted a proposed rule change to, among other things, temporarily change the COPS contributor compensation structure

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78 FR 69168 (November 18, 2013) (SR–CBOE–2013–104); 34–72621 (July 16, 2014), 79 FR 42616 (July 22, 2014) (SR–CBOE–2014–057); 34–74159 (January 28, 2015), 80 FR 5863 (February 23, 2015) (SR–CBOE–2015–007); 34–74937 (May 12, 2015), 80 FR 28319 (May 18, 2015) (SR–CBOE–2015–046); and 34–76888 (January 13, 2016), 81 FR 12 (January 20, 2016) (SR–CBOE–2015–122).

[4] *See* Securities Exchange Act Release Nos. 34–67813 (September 10, 2012), 77 FR 56903 (September 14, 2012) (SR–CBOE–2012–083); 34–67928 (September 26, 2012), 77 FR 60161 (October 2, 2012) (SR–CBOE–2012–090); 34–70705 (October 17, 2013), 78 FR 63265 (October 23, 2013) (SR–CBOE–2013–097); 34–70845 (November 12, 2013), 78 FR 69168 (November 18, 2013) (SR–CBOE–2013–104); 34–72621 (July 16, 2014), 79 FR 42616 (July 22, 2014) (SR–CBOE–2014–057); 34–74159 (January 28, 2015), 80 FR 5863 (February 23, 2015) (SR–CBOE–2015–007); 34–74937 (May 12, 2015), 80 FR 28319 (May 18, 2015) (SR–CBOE–2015–046); and 34–76888 (January 13, 2016), 81 FR 12 (January 20, 2016) (SR–CBOE–2015–122).

[5] "End of day" refers to data that is distributed prior to the opening of the next trading day.

[6] "Historical" COPS data consists of COPS data that is over one month old (*i.e.*, copies of the "end-of-day" COPS file that are over one month old).

[7] FLEX options are exchange traded options that provide investors with the ability to customize basic option features including size, expiration date, exercise style, and certain exercise prices.

[8] "Indicative" values are indications of potential market prices only and as such are neither firm nor the basis for a transaction.

[9] Current FLEX options open interest spans over 2,000 series on over 300 different underlying securities.

[10] These values are theoretical in that they are indications of potential market prices for options that have not traded (*i.e.*, do not yet exist). Market participants sometimes express option values in percentage terms rather than in dollar terms because they find it is easier to assess the change, or lack of change, in the marketplace from one day to the next when values are expressed in percentage terms.

[11] Exotic options are options which are generally traded OTC and are more complex than standard options, usually relating to determination of payoff. An exotic option may also include a non-standard underlying instrument, developed for a particular client or for a particular market.

[12] The fees that MDX charges for COPS Data are set forth on the Price List on the MDX Web site (*www.marketdataexpress.com*). MDX currently charges a fee per option per day for "end-of-day" COPS data. The amount of the fee is reduced based on the number of options valuations purchased.

from a revenue sharing plan to a fixed payment structure for a six-month period ("Fixed Payment Period").[13] In May 2015, the Exchange submitted a proposed rule change to change the COPS contributor compensation structure for the remainder of 2015.[14] Pursuant to that proposed rule change, as of May 1, 2015, all revenue from the sale of COPS Data was paid to COPS contributors, with revenue divided equally among COPS contributors. In December 2015, (sic) As described in that proposed rule change, MDX would transition back to the revenue share plan described above on January 1, 2016. In December 2015, the Exchange submitted a proposed rule change to extend the temporary suspension through June 30, 2016.[15]

Proposal

The Exchange proposes to re-implement the temporary suspension described above through the end of the year. As such, all revenue from the sale of COPS Data would be paid to COPS contributors through December 31, 2016. As before, the revenue would continue to be divided equally among COPS contributors. The Exchange had hoped that at the end June 2016, COPS revenue would be at a level such that the COPS contributors would receive a revenue share roughly in line with the fixed payments they received during the Fixed Payment Period. This has not yet occurred. The payments to COPS contributors are intended to, at a minimum, help COPS contributors cover their costs of producing valuations for COPS while the Exchange continues to grow the COPS business.

2. Statutory Basis

The Exchange believes the proposed rule change is consistent with the Securities Exchange Act of 1934 (the "Act") and the rules and regulations thereunder applicable to the Exchange and, in particular, the requirements of Section 6(b) of the Act.[16] Specifically, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [17] requirements that the rules of an exchange be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest. Additionally, the Exchange believes the proposed rule change is consistent with the Section 6(b)(5) [18] requirement that the rules of an exchange not be designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes the proposed rule change is not designed to permit unfair discrimination between CBOE TPHs because all COPS data revenue would be divided equally among TPH contributors through December 31, 2016. The Exchange believes the proposed rule change is consistent with the protection of investors and the public interest in that it would provide incentive for all of the COPS contributors to participate in COPS while the Exchange continues to grow the COPS business, thereby helping to maintain the quality of COPS Data.

B. Self-Regulatory Organization's Statement on Burden on Competition

CBOE does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes the proposal is procompetitive in that it will incentivize COPS contributors to continue producing quality valuations to help keep COPS competitive with other similar market data products.[19]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange neither solicited nor received comments on the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act [20] and paragraph (f)(2) of Rule 19b–4 [21] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission will institute proceedings to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov. Please include File Number SR–CBOE–2016–059 on the subject line.*

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–CBOE–2016–059. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–CBOE–2016–059 and should be submitted on or before September 7, 2016.

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[13] *See* Securities Exchange Act Release No. 34–72621 (July 16, 2014), 79 FR 42616 (July 22, 2014) (SR–CBOE–2014–057).

[14] Securities Exchange Act Release No. 34–74937 (May 12, 2015), 80 FR 28319 (May 18, 2015) (SR–CBOE–2015–046).

[15] Securities Exchange Act Release No. 34–76888 (January 13, 2016), 81 FR 12 (January 20, 2016) (SR–CBOE–2015–122). The Exchange is not proposing to eliminate the revenue share plan, but rather re-implement the temporary suspension as described in this rule filing.

[16] 15 U.S.C. 78f(b).

[17] 15 U.S.C. 78f(b)(5).

[18] *Id.*

[19] Market data vendors including SuperDerivatives, Markit, Prism, and Bloomberg's BVAL service produce option value data that is similar to COPS Data. The Options Clearing Corporation ("OCC") also produces FLEX option value data that is similar to the FLEX option value data that is included in COPS.

[20] 15 U.S.C. 78s(b)(3)(A).

[21] 17 CFR 240.19b–4(f)(2).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[22]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19584 Filed 8–16–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78550; File No. SR–IEX–2016–09]

Self-Regulatory Organizations; Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change Related to Transaction and Regulatory Fees

August 11, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act''),[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 5, 2016, the Investors Exchange LLC (''IEX'' or the ''Exchange'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 (''Act''),[4] and Rule 19b–4 thereunder,[5] Investors Exchange LLC (''IEX'' or ''Exchange'') is filing with the Securities and Exchange Commission (''Commission'') a proposed rule change to (i) adopt transaction fees applicable to Members[6] of the Exchange pursuant to IEX Rule 15.110(a) and (c) (''Fee Schedule''), and (ii) adopt regulatory fees related to the Central Registration Depository (''CRD system''), which will be collected by the Financial Industry Regulatory Authority, Inc. (''FINRA'') pursuant to IEX Rule 15.110(a). The Exchange proposes to implement the rule change effective with its exchange launch. The text of the proposed rule change is available at the Exchange's Web site at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement [sic] may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Transaction Fees

The Exchange proposes to implement a fee schedule applicable to use of the Exchange commencing on the date it begins operating as a national securities exchange. The Exchange currently intends to commence operations as a national securities exchange on or about August 19, 2016. IEX proposes to implement the Fee Schedule described herein, which will be applicable to transactions executed in all trading sessions, effective with its exchange launch.

(A) Displayed Match Fee

The Exchange does not propose to charge any fee to Members for executions on IEX that include resting interest with displayed priority (*i.e.,* an order or portion of a reserve order that is booked and ranked with display priority on the Order Book either as the IEX best bid or best offer (''BBO'') or at a worse price on the Order Book) for both the liquidity adding and liquidity removing order.[7]

(B) Non-Displayed Match Fee

The Exchange proposes to charge $0.0009 per share (or 0.30% of the total dollar value of the transaction for securities priced below $1.00) to Members for executions on IEX that include resting interest with non-displayed priority (*i.e.,* an order or portion of a reserve order that is booked and ranked with non-display priority on the Order Book either at the NBBO midpoint or at a worse price on the Order Book) for both the liquidity adding and liquidity removing order,[8] with the exception of executions on the Exchange where the adding and removing order originated from the same Exchange Member and displayable orders removing non-displayed liquidity upon entry, each as described below.

Notwithstanding the foregoing, the Exchange does not propose to charge any fee to Members for executions on IEX that involve taking resting interest with non-displayed priority where (a) the liquidity removing order was displayable (*i.e.,* the order would have booked and displayed if posted to the Order Book) and (b) on a monthly basis, at least 90% of the liquidity removing Member's aggregate executions of displayable orders added liquidity during such calendar month. However, in such transactions, the non-displayed liquidity adding interest will be subject to the Non-Displayed Match Fee described above.

(C) Internalization Fee

The Exchange does not propose to charge any fee to Members for executions on IEX when the adding and removing order originated from the same Exchange Member.[9] Orders from different market participant identifiers of the same broker dealer, with the same Central Registration Depository registration number, would be treated as originating from the same Exchange Member.

(D) Routing Charges

The Exchange proposes to pass the fee or rebate from an away trading center to the Member and charge a fee of $0.0001 per share for all routing options offered by the Exchange. All charges for routing are applicable only in the event that an order is executed on an away trading center.[10]

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[22] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] 15 U.S.C. 78s(b)(1).

[5] 17 CRF [sic] 240.19b–4.

[6] *See,* IEX Rule 1.160(s).

[7] This pricing is referred to by the Exchange as ''Displayed Match Fee'' on the proposed Fee Schedule with a Fee Code of 'L' to be provided by the Exchange on execution reports.

[8] This pricing is referred to by the Exchange as ''Non-Displayed Match Fee'' on the proposed Fee Schedule with a Fee Code of 'I' to be provided by the Exchange on execution reports.

[9] This pricing is referred to by the Exchange as ''Internalization Fee'' on the proposed Fee Schedule with a Fee Code of 'S' to be provided by the Exchange on execution reports.

(E) Other Fees

The Exchange does not propose to charge fees for membership, connectivity port fees, or market data.

Regulatory Fees

IEX is proposing to adopt certain regulatory fees under Rule 15.110(a) related to the CRD system, which are collected by FINRA.[11] As proposed, FINRA will collect and retain certain regulatory fees via the CRD system for the registration of persons associated with an Exchange Members [sic] that are not also FINRA members. The CRD system fees are use-based and there is no distinction in the cost incurred by FINRA if the user is a FINRA member or a member of an exchange but not a FINRA member. Accordingly, IEX is proposing to adopt the fees under IEX Rule 15.110(a) to mirror those assessed by FINRA pursuant to Section (4) of Schedule A to the FINRA By-Laws. As proposed, the fees are as follows: [12]

(1) $100 for each initial Form U4 filed for the registration of a representative or principal;

(2) $110 for the additional processing of each initial or amended Form U4, Form U5 or Form BD that includes the initial reporting, amendment, or certification of one or more disclosure events or proceedings;

(3) $45 annual for each of the Member's registered representatives and principals for system processing;

(4) $15 for processing and posting to the CRD system each set of fingerprint cards submitted electronically by the Member, plus a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints;

(5) $30 for processing and posting to the CRD system each set of fingerprint cards submitted in non-electronic format by the Member, plus a pass-through of any other charge imposed by the United States Department of Justice for processing each set of fingerprints; and

(6) $30 for processing and posting to the CRD system each set of fingerprint results and identifying information that has been processed through a self-regulatory organization other than FINRA.

2. Statutory Basis

Transaction Fees

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b) [13] of the Act in general, and furthers the objectives of Sections [sic] 6(b)(4) [14] of the Act, in particular, in that it is designed to provide for the equitable allocation of reasonable dues, fees and other charges among its Members and other persons using its facilities. Additionally, IEX believes that the proposed fees are consistent with the investor protection objectives of Section 6(b)(5) [15] of the Act in particular in that they are designed to promote just and equitable principles of trade, to remove impediments to a free and open market and national market system, and in general to protect investors and the public interest.

The proposed Fee Schedule set forth herein is designed to minimize incentives for trading and order routing decisions based solely on rebates that could create conflicts of interest by skewing economic incentives related to such decisions. In addition, by not offering rebates, IEX has simplified its order type offering to avoid order types designed to assure receipt of a rebate.[16] By contrast, as proposed, IEX will charge relatively low fees for all executed shares, and which will be significantly lower than many other exchange fees charged for removing (or taking) liquidity.[17] Moreover, IEX believes that adders of liquidity can be incentivized to rest shares by offering a market model and order types designed to protect their interests as opposed to the payment of a rebate.

IEX believes that it is appropriate, reasonable and consistent with the Act, to charge the $0.0009 per share Non-Displayed Match Fee, because it is within the transaction fee range charged by other exchanges.[18] IEX also believes that it is appropriate, reasonable and consistent with the Act, not to charge a fee for transactions that include execution of an order with displayed priority on the Order Book. This fee structure is designed to incentivize Members to send IEX aggressively priced displayable orders, thereby contributing to price discovery and consistent with the overall goal of enhancing market quality. IEX believes that not charging a fee for both the liquidity adder and remover is equitable and not unfairly discriminatory because it is designed to facilitate execution of, and enhance trading opportunities for, displayable orders, thereby further incentivizing entry of displayed orders.

In addition, the Exchange believes that it is appropriate, and consistent with the Act, to not charge a fee to Members with respect to displayable orders that remove non-displayed liquidity upon entry so long as at least 90% of the Member's aggregate executed shares of displayable orders added liquidity during the month in question. This flexibility is designed to address limited inadvertent liquidity removal for Exchange Members who are largely adding displayed liquidity. Under these circumstances, the Member generally intends to add displayed liquidity on IEX, and the Exchange therefore believes that it is appropriate to provide a fee incentive to such order, subject to the 90% limitation described herein, to further encourage aggressively priced displayed orders. The Exchange also believes that it is appropriate, reasonable and consistent with the Act, to charge the $0.0009 per share Non-Displayed Match Fee to Members for the resting, non-displayed order that matches with the displayable order under such circumstances because the reduced fee for Members entering displayable orders removing non-displayed liquidity is a narrowly drawn incentive to address unintended consequences. Accordingly, the Exchange believes that it is appropriate to charge the $0.0009 per share Non-Displayed Match Fee for such orders. The Exchange also notes that most other national securities exchanges charge different fees to members for adding and removing liquidity, and that this aspect of IEX's proposed Fee Schedule does not raise any new or novel issues that have not previously been considered by the Commission in connection with the fees of other national securities exchanges.[19]

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[10] The Exchange will provide the Fee Code from away market centers on execution reports of routed transactions. In the proposed Fee Schedule, the Fee Code of "Alpha" is used to indicate this behavior.

[11] The CRD system is the central licensing and registration system for the U.S. securities industry. The CRD system enables individuals and firms seeking registration with multiple states and self-regulatory organizations to do so by submitting a single form, fingerprint card and a combined payment of fees to FINRA. Through the CRD system, FINRA maintains the qualification, employment and disciplinary histories of registered associated persons of broker dealers.

[12] The Exchange has only adopted the CRD system fees charged by FINRA to Non-FINRA Members when such fees are applicable. In this regard, certain FINRA CRD system fees and requirements are specific to FINRA members, but do not apply to IEX Members that are not also FINRA members. IEX Members that are also FINRA members are charged CRD system fees according to Section (4) of Schedule A to the FINRA By-Laws.

[13] 15 U.S.C. 78f.

[14] 15 U.S.C. 78f(b)(4).

[15] 15 U.S.C. 78f(b)(5).

[16] In an address on equity market structure on June 5, 2014, Chair Mary Jo White called upon the exchanges to conduct a comprehensive review of their order types and how they operate, as well as to "consider appropriate rule changes to help clarify the nature of their order types and how they interact with each other, and how they support fair, orderly, and efficient markets." (*See,* speech by Chair Mary Jo White at Sandler O'Neill & Partners, L.P. Global Exchange and Brokerage Conference, New York, N.Y., available at *http://www.sec.gov/News/Speech/Detail/Speech/1370542004312*)

[17] For example, the New York Stock Exchange trading fee schedule on its public Web site reflects fees to "take" liquidity ranging from $0.0024–$0.00275 depending on the type of market participant, order and execution (*See, https://www.nyse.com/markets/nyse/trading-info/fees*). The Nasdaq Stock Market ("Nasdaq") trading fee schedule on its public Web site reflects fees to "remove" liquidity ranging from $0.0030 per share for shares executed at or above $1.00 or 0.30% of total dollar volume for shares executed below $1.00 (*See, http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2*). BATS BZX Exchange ("BZX") trading fee schedule on its public Web site reflects fees for "removing" liquidity ranging from $0.0030 for shares executed at or above $1.00 or 0.30% of total dollar volume for shares executed below $1.00, subject to certain limited exceptions for orders trading in the opening, IPO or halt auctions BZX listed securities (*See, https://www.batstrading.com/support/fee_schedule/bzx/*).

[18] *Id.*

With respect to internalized trades, the proposal to charge no fee is designed to incentivize Members (and their customers) to send orders to IEX that may otherwise be internalized off exchange. As broker operated ATSs and internalization mechanisms have proliferated to account for nearly 40% of trading volume,[20] natural investor trading interest has become increasingly dispersed across these venues, while the overall trading volume on regulated exchanges has declined.[21] IEX believes that one of the factors driving broker decisions to trade away from regulated exchanges has been exchange access fees. Accordingly, this fee structure is designed with the goal to increase resultant order interaction on IEX. In this regard, IEX believes that increased liquidity on IEX would have several benefits to investors in securities traded on IEX. First, it would increase opportunities for investors' orders to interact directly, thereby concurrently reducing the need for unnecessary intermediation and the associated implicit costs, including potential information leakage and gaming. Second, to the extent Exchange Members post more displayed orders on IEX, price discovery would be enhanced drawing more natural trading interest to the public markets which would deepen liquidity and dampen the impact of shocks from liquidity demand. Third, orders executed on IEX rather than being internalized on broker-operated platforms, will have the benefit of exchange transparency, regulation, and oversight. Additionally, because IEX prices orders based on direct market data feeds of protected markets,[22] the quality of executions on IEX may be enhanced compared to orders that are internalized on certain broker-operated platforms that price orders based on SIP market data feeds.

It is important to note that orders entered by the same broker (that by their terms could be executable against each other) are not guaranteed to be matched against each other, and each order is individually at market risk for execution against contra-side orders from other Members. Moreover, Members sending orders eligible for this fee structure are subject to all existing IEX and FINRA rules applicable to customer orders, including without limitation those pertaining to wash sales, best execution, and customer priority. (*See* for example, Chapter 10 of the IEX Rules and FINRA Rules 5210, 5310 and 5320).

Moreover, IEX believes that there are precedents for exchanges to charge fees that distinguish between different types of members to incentivize certain types of members. These fee structures may discriminate in favor of certain types of members but not in an unfairly discriminatory manner in violation of the Act. In this regard, most other exchanges offer reduced fees to members that reach certain volume based tiers. Such fee structures, while nominally available to all members, are targeted to incentivize larger members with enough volume to reach the volume-based tiers. For example, the NYSE fee schedule provides rebates of up to $0.0022 per share for members generally that provide greater than 1.10% of consolidated average trading volume compared to no rebate for firms that do not reach specified volume tiers. And NYSE floor brokers, which have no unique obligations to the market, receive higher rebates at certain volume levels, as well as lower take fees, compared to NYSE member firms generally.[23]

Similarly, the IEX fee structure is designed to incentivize Members to send orders to a regulated exchange and enable IEX to compete more effectively with internalizers and dark pools that provide internalized matching. Notwithstanding that IEX will not pay for order flow, the Exchange believes that some Members may nonetheless choose to direct order flow to IEX as a regulated exchange in order to benefit from real-time reporting and regulatory oversight, and that not charging a fee will help IEX to compete for such order flow. The Exchange does not believe that this fee incentive is unfairly discriminatory because it is available to any IEX Member, consistent with applicable FINRA and IEX rules, and potentially benefits all members because the fee incentive may result in increased order flow and liquidity in IEX. As noted above, internalization on IEX is not guaranteed, and the additional order flow that does not internalize is available to trade by all Members, and would enhance price discovery if such order flow results in more displayed orders.

Trading on the IEX alternative trading system ("ATS") directly supports the Exchange's contention that the proposed pricing structure will provide benefits to Members generally and is not unfairly discriminatory. IEX has offered comparable pricing on its ATS. Between January 1, 2016 and June 30, 2016, internalized transactions occurred across 66 of 145 ATS subscribers with a range of business models (*e.g.,* full service, agency, and retail broker-dealers).[24] During the period January 1, 2016 through June 30, 2016, approximately 454 million shares internalized on the IEX ATS. For those transactions on the IEX ATS that included self-matched volume, the liquidity removing orders also executed against approximately 63 million resting shares of other subscribers.[25] Thus, IEX does not believe that the internalization fee incentive has had an unfairly discriminatory impact in practice, since internalized transactions occurred across a large number of different types of subscribers, providing collateral liquidity benefits to other subscribers.

Additionally, the Exchange believes that its proposed fee codes, to be provided on execution and routing reports, will provide transparency and predictability to Members as to applicable transaction fees. In this regard, IEX notes that Members will be able to maintain a tally of executions of displayable orders eligible for no fee for taking non-displayed liquidity by calculating, on a monthly basis, whether the proportion of their executed displayable orders that added liquidity is 90% or more of their total monthly volume of executed displayable orders. Using IEX execution reports, Members can calculate whether the sum of executions with Fee Code L and a Last Liquidity Indicator (FIX tag 851) of '1' (Added Liquidity), divided by the sum of executions with Fee Code L is at least 90%.

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[19] *See,* for example *https://www.nyse.com/markets/nyse/trading-info/fees, http://nasdaqtrader.com/Trader.aspx?id=PriceListTrading2,* and *https://www.batstrading.com/support/fee_schedule/bzx/*).

[20] *See,* for example, BATS Market Volume Summary for June 14, 2016 available at *http://batstrading.com/market_summary/.*

[21] *See,* for example a speech by former Commissioner Luis A. Aguilar on May 11, 2015 entitled "U.S. Equity Market Structure: Making Our Markets Work Better for Investors" (available at *http://www.sec.gov/news/statement/us-equity-market-structure.html#_ednref1*), and speech by Commission Chair Mary Jo White on June 5, 2014 entitled "Enhancing our Equity Market Structure" (available at *http://www.sec.gov/News/Speech/Detail/Speech/1370542004312#_ednref17*).

[22] *See* IEX Rule 11.410(a)(2)–(4), which describes IEX's use of proprietary market data feeds and those of the Securities Information Processors.

[23] *See, https://www.nyse.com/markets/nyse/trading-info/fees.*

[24] Between January 1, 2016 and June 30, 2016, only 2.97 percent of overall subscribers' volume was from internalized transactions.

[25] During the same period, there were also approximately 578 million unexecuted shares from the incoming orders that self-matched.

In summary, IEX believes that the proposed fee structure for internalized transactions is reasonable, fair and equitable, and not an unfairly discriminatory allocation of fees because it will provide all Members with incentives not to avoid sending orders to IEX that will contribute to enhanced liquidity and price discovery on a regulated exchange. While not all Members necessarily will have the ability to directly benefit from the proposed fee structure for internalized transactions, as noted above internalization is not guaranteed so IEX believes that Members generally may indirectly benefit from an increase in order flow that does not internalize on IEX, as has been the case on the ATS.

With respect to orders routed to other exchanges, the proposal to pass through fees charged by such other away trading centers for executed shares plus charge a fee of $0.0001 payable to IEX is a reasonable, fair and equitable, and not an unfairly discriminatory allocation of fees because the fee is applicable to all Members in an equivalent manner. The $0.0001 fee payable to IEX is not inconsistent with the fees charged by other exchanges for routed orders, since many of their routing fees are variable based on the fees and rebates charged by such other venues.[26] Accordingly, the IEX proposed approach raises no new or novel issues.

As described more fully below in the Exchange's statement regarding the burden on competition, the Exchange believes that it is subject to significant competitive forces, and that its proposed fee structure is an appropriate effort to address such forces.

IEX also believes that not charging a fee for membership, connectivity or market data is reasonable because it may incentivize broker-dealers to become members of the Exchange and to therefore direct order flow to IEX. As a new exchange, IEX will operate in a highly competitive environment, and not charging fees for such services and access is designed to enable it to compete effectively.

In conclusion, the Exchange also submits that its proposed fee structure satisfies the requirements of Sections 6(b)(4) and 6(b)(5) of the Act for the reasons discussed above in that it does not permit unfair discrimination between customers, issuers, brokers, or dealers, and is designed to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system. For the foregoing reasons, the Exchange believes that its simplified fee structure is consistent with the Act, in that it is designed to promote just and equitable principles of trade, to remove impediments to a free and open market and national market system and in general to protect investors and the public interest.

Regulatory Fees

IEX believes that the proposed rule change is consistent with the provisions of Section 6(b)[27] of the Act in general, and furthers the objectives of Section 6(b)(4)[28] of the Act, in particular, in that it provides for the equitable allocation of reasonable fees and other charges among its members, and does not unfairly discriminate between customers, issuers, brokers and dealers. All similarly situated Members are subject to the same fee structure, and every Member firm must use the CRD system for registration and disclosure.

The proposed fees are reasonable because they are identical to those adopted by FINRA for use of the CRD system for disclosure and the registration of associated persons of FINRA members.[29] As FINRA noted in its filing adopting its existing fees, it believes the fees are reasonable based on the increased costs associated with operating and maintaining the CRD system, and listed a number of enhancements made to the CRD system since the last fee increase, including: (1) Incorporation of various uniform registration form changes; (2) electronic fingerprint processing; (3) Web EFT™, which allows subscribing firms to submit batch filings to the CRD system; (4) increases in the number and types of reports available through the CRD system; and (5) significant changes to BrokerCheck, including making BrokerCheck easier to use and expanding the amount of information made available through the system.[30] These increased costs are similarly borne by FINRA when a member of IEX that is not a member of FINRA uses the CRD system, so the fees collected for such use should mirror the fees assessed on FINRA members, as is proposed by IEX. FINRA further noted its belief that the proposed fees are reasonable because they help to ensure the integrity of the information in the CRD system, which is important because the Commission, FINRA, other self-regulatory organizations and state securities regulators use the CRD system to make licensing and registration decisions, among other things.[31]

The Exchange also believes that the proposed fees, like FINRA's fees, are consistent with an equitable allocation of fees because the fees will apply equally to all individuals and members required to report information to the CRD system. Thus, those members that register more individuals or submit more filings through the CRD system will generally pay more in fees than those members that use the CRD system to a lesser extent. In addition, the proposed fees, like FINRA's fees, are equitable and not unfairly discriminatory because they will result in the same regulatory fees being charged to all IEX Members required to report information to the CRD system and for services performed by FINRA, regardless of whether or not such Member is a FINRA member.

B. Self-Regulatory Organization's Statement on Burden on Competition

Transaction Fees

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed rule change will impose any burden on intermarket competition that is not necessary or appropriate in furtherance of the purposes of the Act. To the contrary, the Exchange believes that the proposed pricing structure will increase competition and hopefully draw additional volume to the Exchange. The Exchange will operate in a highly competitive market in which market participants can readily favor competing venues if fee schedules at other venues are viewed as more favorable. As a new exchange, IEX expects to face intense competition from existing exchanges and other non-exchange venues that provide markets for equities trading. Consequently, the Exchange believes that the degree to which IEX fees could impose any burden on competition is extremely limited, and does not believe that such fees would burden competition of Members or competing venues in a manner that is not necessary or appropriate in furtherance of the purposes of the Act.

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[26] *See,* for example, Nasdaq Stock Market Rule 7018(a)(1).

[27] 15 U.S.C. 78f.

[28] 15 U.S.C. 78f(b)(4).

[29] *See* Securities Exchange Act Release No. 67247 (June 25, 2012), 77 FR 38866 (June 29, 2012) (SR–FINRA–2012–30).

[30] *See supra,* note 27 [sic], at 77 FR 38866, 38868.

[31] *See supra* [sic], at 77 FR 38866, 38868.

The Exchange does not believe that the proposed rule change will impose any burden on intramarket competition that is not necessary or appropriate in furtherance of the purposes of the Act because, while different fees are assessed in some circumstances, these different fees are not based on the type of Member entering the orders that match but on the type of order entered and all Members can submit any type of order. Further, the proposed fees are intended to encourage market participants to bring increased volume to the Exchange, which benefits all market participants.

Regulatory Fees

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes that the proposed fees will result in the same regulatory fees being charged to all Members required to report information to the CRD system and for services performed by FINRA, regardless of whether or not such Members are FINRA members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[32] and paragraph (f) of Rule 19b–4[33] thereunder. At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2016–09 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2016–09. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml).* Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2016–09, and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[34]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19581 Filed 8–16–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78556; File No. SR–NYSE–2016–45]

Self-Regulatory Organizations; New York Stock Exchange LLC; Notice of Filing of Proposed Rule Change Amending the Co-location Services Offered by the Exchange To Add Certain Access and Connectivity Fees

August 11, 2016.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 29, 2016, New York Stock Exchange LLC ("NYSE" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of the Substance of the Proposed Rule Change

The Exchange proposes to amend the co-location services offered by the Exchange as follows: (1) To provide additional information regarding the access to trading and execution services and connectivity to data provided to Users with local area networks available in the data center; and (2) to establish fees relating to User's access to trading and execution services; connectivity to data feeds and to testing and certification feeds; access to clearing; and other services. In addition, this proposed rule change reflects changes to the Exchange's Price List related to these co-location services. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

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[32] 15 U.S.C. 78s(b)(3)(A).

[33] 17 CFR 240.19b–4(f).

[34] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the co-location[4] services offered by the Exchange as follows: (1) To provide additional information regarding the access to trading and execution services and connectivity to data provided to Users[5] with local area networks available in the data center; and (2) to establish fees relating to Users' access to trading and execution services; connectivity to data feeds and to testing and certification feeds; access to clearing; and other services.

More specifically, the Exchange proposes to revise the Price List to include:

a. A more detailed description of the access to the trading and execution systems of the Exchange and its Affiliate SROs (the "Exchange Systems") and connectivity to certain market data products (the "Included Data Products") that Users receive with connections to the Liquidity Center Network ("LCN") and internet protocol ("IP") network, local area networks available in the data center;

b. fees for connectivity to:

- Certain other market data products of the Exchange and its Affiliate SROs (the "Premium NYSE Data Products" and, together with the Included Data Products, the "NYSE Data Products");
- access to the execution systems of third party markets and other content service providers ("Third Party Systems");
- data feeds from third party markets and other content service providers (the "Third Party Data Feeds");
- third party testing and certification feeds;
- Depository Trust & Clearing Corporation ("DTCC") services; and

c. fees for virtual control circuits ("VCCs") between two Users. VCCs are unicast connections between two participants over dedicated bandwidth.[6]

The Exchange provides access to the Exchange Systems and Third Party Systems (together, "Access") and connectivity to NYSE Data Products, Third Party Data Feeds, third party testing and certification feeds, and DTCC (collectively, "Connectivity") as conveniences to Users. Use of Access or Connectivity is completely voluntary, and several other access and connectivity options are available to a User. As alternatives to using the Access and Connectivity provided by the Exchange, a User may access or connect to such services and products through another User or through a connection to an Exchange access center outside the data center, third party access center, or third party vendor. The User may make such connection through a third party telecommunication provider, third party wireless network, the Exchange's Secure Financial Transaction Infrastructure ("SFTI") network, or a combination thereof.

Similarly, the Exchange provides VCCs as a convenience to Users. Use of a VCC is completely voluntary. As an alternative to an Exchange-provided VCC, a User may connect to another User through a fiber connection ("cross connect").[7]

Access to Exchange Systems and Connectivity to Included Data Products

As the Exchange has previously stated, a User's connection to the LCN or IP network provides it access to the Exchange Systems and Exchange market data products.[8] More specifically, when a User purchases access to the LCN or IP network through purchase of a 1, 10, or 40 Gb LCN circuit, a 10 Gb LX Circuit, bundled network access, Partial Cabinet Solution bundle, or 1, 10 or 40 Gb IP network access,[9] as part of the purchase it receives access to the Exchange Systems and connectivity to any Included Data Products that it selects.[10] The Exchange proposes to revise the Price List to provide a more detailed description of the access to the Exchange Systems and connectivity to Included Data Products that comes with connections to the LCN or IP network.[11]

Access to certification and testing feeds comes with the purchase of access to the Exchange Systems and connectivity to many of the NYSE Data Products. Such feeds, which are solely used for certification and testing and do not carry live production data, are only available over the IP network.[12] Certification feeds are used to certify that a User conforms to any relevant technical requirements for receipt of data or access to Exchange Systems. Test feeds provide Users an environment in which to conduct tests with non-live data, including testing for upcoming Exchange releases and product enhancements or the User's own software development.

The Exchange offers connectivity to NYSE Data Products in three forms: as a resilient feed, as "Feed A" or as "Feed B." Resilient feeds include two copies of the same feed, for redundancy purposes. Feed A and Feed B are identical feeds.[13]

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[4] The Exchange initially filed rule changes relating to its co-location services with the Securities and Exchange Commission ("Commission") in 2010. *See* Securities Exchange Act Release No. 62960 (September 21, 2010), 75 FR 59310 (September 27, 2010) (SR–NYSE–2010–56) (the "Original Co-location Filing"). The Exchange operates a data center in Mahwah, New Jersey (the "data center") from which it provides co-location services to Users.

[5] For purposes of the Exchange's co-location services, a "User" means any market participant that requests to receive co-location services directly from the Exchange. *See* Securities Exchange Act Release No. 76008 (September 29, 2015), 80 FR 60190 (October 5, 2015) (SR–NYSE–2015–40). As specified in the Price List, a User that incurs co-location fees for a particular co-location service pursuant thereto would not be subject to co-location fees for the same co-location service charged by the Exchange's affiliates NYSE MKT LLC ("NYSE MKT") and NYSE Arca, Inc. ("NYSE Arca" and, together with NYSE MKT, the "Affiliate SROs"). *See* Securities Exchange Act Release No. 70206 (August 15, 2013), 78 FR 51765 (August 21, 2013) (SR–NYSE–2013–59).

[6] Information flows over existing network connections in two formats: "unicast" format, which is a format that allows one-to-one communication, similar to a phone line, in which information is sent to and from the Exchange; and "multicast" format, which is a format in which information is sent one-way from the Exchange to multiple recipients at once, like a radio broadcast.

[7] *See* Original Co-location Filing, *supra* note 4, at 59311 and Securities Exchange Act Release No. 74222 (February 6, 2015), 80 FR 7888 (February 12, 2015) (SR–NYSE–2015–05) (notice of filing and immediate effectiveness of proposed rule change to include IP network connections and fiber cross connects between a User's cabinet and non-User's equipment as co-location services) (the "IP Network Release").

[8] *See* Original Co-location Filing, *supra* note 4, at 59311 ("According to NYSE, SFTI and LCN both provide Users with access to the Exchange's trading and execution systems and to the Exchange's proprietary market data products.") and IP Network Release, *supra* note 7, at 7889 ("Like the LCN, the IP network provides Users with access to the Exchange's trading and execution systems and to the Exchanges' proprietary market data products."). The IP network was previously sometimes referred to as SFTI. *See id.*

[9] *See* Securities Exchange Act Release Nos. 70888 (November 15, 2013), 78 FR 69907 (November 21, 2013) (SR–NYSE–2013–73); 72721 (July 30, 2014), 79 FR 45562 (August 5, 2014) (SR–NYSE–2014–37); 76369 (November 5, 2015), 80 FR 70027 (November 12, 2015) (SR–NYSE–2015–54); and 77072 (February 5, 2016), 81 FR 7394 (February 11, 2016) (SR–NYSE–2015–53).

[10] As discussed below, in order to connect to an Included Data Product, a User must have entered into a contract with the provider of the data feed. Similarly, in order to access an Exchange System, the User must have authorization from the Exchange or the relevant Affiliate SRO.

[11] Because each Included Data Product uses part of a User's bandwidth, a User may wish to limit the number of Included Data Products that it receives to those that it requires. The Exchange notes that connectivity to the LCN and IP network also includes connectivity to Exchange Systems, as discussed under "Connectivity to Exchange Systems," below. *See also* note 8, *supra*.

[12] A User that does not have an IP network connection may obtain an IP network circuit for purposes of testing and certification for free for three months. *See* IP Network Release, *supra* note 7, at 7889. A User that opted to obtain connectivity to NYSE Data Products through another User, a telecommunication provider, third party wireless network, or the SFTI network would receive the corresponding testing and certification feeds.

Connectivity to Exchange Systems

As the Exchange has previously stated, Users' connections to the LCN or IP networks include access to Exchange Systems.[14] Accordingly, the Exchange proposes to add language to its Price List stating the following:

> When a User purchases access to the LCN or IP network, it receives the ability to connect to the trading and execution systems of the NYSE, NYSE MKT and NYSE Arca (Exchange Systems), subject, in each case, to authorization by the NYSE, NYSE MKT or NYSE Arca, as applicable. Such connectivity includes access to the customer gateways that provide for order entry, order receipt (*i.e.* confirmation that an order has been received), receipt of drop copies and trade reporting (*i.e.* whether a trade is executed or cancelled), as well as for sending information to shared data services for clearing and settlement. A User can change the connections it receives at any time, subject to authorization. A User does not have to purchase access to the LCN or IP network in order to obtain connectivity to Exchange Systems.

Connectivity to Included Data Products

Currently, there are three categories of data feeds for which the Exchange offers Users connectivity: Included Data Products; Premium NYSE Data Products; and Third Party Data.[15]

The Included Data Products include the data feeds disseminated by the Consolidated Tape Association ("CTA") (such data feeds, the "NMS feeds"). CTA is responsible for disseminating consolidated, real-time trade and quote information in NYSE listed securities (Network A) and NYSE MKT, NYSE Arca and other regional exchanges' listed securities (Network B) pursuant to a national market system plan.[16] The NMS feeds include the Consolidated Tape System and Consolidated Quote System data streams, as well as Options Price Reporting Authority feeds.

In order to connect to an Included Data Product, a User enters into a contract with the provider of such data, pursuant to which the User is charged for the Included Data Product. After the User and data provider enter into the contract and the Exchange receives authorization from the provider of the data feed, the Exchange provides the User with connectivity to the Included Data Product over the User's LCN or IP network port. The Exchange does not charge the User separately for such connectivity to the Included Data Product, as it is included in the purchase of the access to the LCN or IP network.

The Included Data Products are available over both the LCN and IP network.[17] For a User that purchases access to the LCN and IP network, the Exchange works with such User to allocate its connectivity to Included Data Products between its LCN and IP network connections. Some Included Data Products require a network connection with a minimum gigabyte ("Gb") size in order to accommodate the feed. Users may connect to an Included Data Product as a resilient feed or as individual Feeds A and B.

The Included Data Products are as follows:

NMS FEEDS

- NYSE:
  - NYSE Alerts
  - NYSE BBO
  - NYSE OpenBook
  - NYSE Order Imbalances
  - NYSE Trades
- NYSE Amex Options
- NYSE Arca:
  - NYSE ArcaBook
  - NYSE Arca BBO
  - NYSE Arca Order Imbalances
  - NYSE Arca Trades
- NYSE Arca Options
- NYSE Bonds
- NYSE MKT:
  - NYSE MKT Alerts
  - NYSE MKT BBO
  - NYSE MKT OpenBook
  - NYSE MKT Order Imbalances
  - NYSE MKT Trades

In addition to the above list of Included Data Products, the Exchange proposes to add the following language to the Price List:

When a User purchases access to the LCN or IP network it receives connectivity to any of the Included Data Products that it selects, subject to any technical provisioning requirements and authorization from the provider of the data feed. Market data fees for the Included Data Products are charged by the provider of the data feed. A User can change the Included Data Products to which it receives connectivity at any time, subject to authorization from the provider of the data feed. The Exchange is not the exclusive method to connect to the Included Data Products.

Connectivity

Connectivity to Premium NYSE Data Products

The Exchange offers Users connectivity to Premium NYSE Data Products from the Exchange and its Affiliate SROs over Users' LCN and IP network connections. The Exchange proposes to revise the Price List to specify the connectivity fees for Premium NYSE Data Products.

The Premium NYSE Data Products are equity market data products that are variants of the equity Included Data Products that integrate, or include data elements from, several Included Data Products.[18] For example, the NYSE Integrated Feed includes, among other things, information available from three of the equity Included Data Products: NYSE OpenBook, NYSE Trades, and NYSE Order Imbalances.[19] The NYSE BQT data feed includes, among other things, certain data elements from six of the equity Included Data Products: NYSE Trades, NYSE BBO, NYSE Arca Trades, NYSE Arca BBO, NYSE MKT Trades, and NYSE MKT BBO.[20]

By contrast, while some of the Included Data Products include data elements from other Included Data Products, no single Included Data Product includes as much data as a Premium NYSE Data Product. With the exception of NYSE Arca Order Imbalances, the equity Included Data

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[13] A User that wants redundancy would either choose a resilient feed or connect to both Feed A and Feed B using two different ports. A User may opt to connect both Feed A and Feed B to the same port, the effect of which would be the same as if the User had connected to a resilient feed.

[14] *See* note 8, *supra*.

[15] The NYSE Data Products and Third Party Data Feeds do not provide access or order entry to the Exchange's execution system.

[16] The Included Data Products do not include connectivity to the data feeds disseminated pursuant to the "Joint Self-Regulatory Organization Plan Governing the Collection, Consolidation and Dissemination of Quotation and Transaction Information for Nasdaq-Listed Securities Traded on Exchanges on an Unlisted Trading Privilege Basis" (the "UTP Plan"). The UTP Plan is responsible for disseminating consolidated, real-time trade and quote information in Nasdaq Stock Exchange LLC listed securities (Network C). Connectivity to data disseminated pursuant to the UTP Plan is available as a Third Party Data Feed.

[17] As noted above, certification and testing feeds included with an Included Data Product are only available over the IP network.

[18] The rule changes establishing the NYSE Integrated Feed and NYSE MKT Integrated Feed were immediately effective in 2015, and the rule change establishing the NYSE Arca Integrated Data Feed was immediately effective in 2011. The NYSE Best Quote & Trades ("NYSE BQT") data feed was approved in 2014. *See* Securities Exchange Act Release Nos. 74128 (Jan. 23, 2015), 80 FR 4951 (Jan. 29, 2015) (SR–NYSE–2015–03) (establishing the NYSE Integrated Feed); 74127 (Jan. 23, 2015), 80 FR 4956 (Jan. 29, 2015) (SR–NYSEMKT–2015–06) (establishing the NYSE MKT Integrated Feed); 65669 (Nov. 2, 2011), 76 FR 69311 (Nov. 8, 2011) (SR–NYSEArca–2011–78) (establishing the NYSE Arca Integrated Feed); and 73553 (Nov. 6, 2014), 79 FR 67491 (Nov. 13, 2014) (SR–NYSE–2014–40) (establishing the NYSE Best Quote & Trades Data Feed).

[19] *See* SR–NYSE–2015–03, *supra* note 18, at 4952.

[20] *See* SR–NYSE–2014–40, *supra* note 18, at 67491.

Products are older feeds than the Premium Data Products.[21]

In order to connect to a Premium NYSE Data Product, a User enters into a contract with the provider of such data, pursuant to which it is charged for the Premium NYSE Data Product. After the data provider and User enter into the contract and the Exchange receives authorization from the data provider, the Exchange provides the User with connectivity to the Premium NYSE Data Product over the User's LCN or IP network port. The Exchange charges the User for the connectivity to the Premium NYSE Data Product. A User only receives, and is only charged for, connectivity to the Premium NYSE Data Product feeds that it selects.

The Premium NYSE Data Products are available over both the LCN and IP network.[22] For a User that purchases access to the LCN and IP network, the Exchange works with such User to allocate its connectivity to Premium NYSE Data Products between its LCN and IP network connections. Some Premium NYSE Data Products require a network connection with a minimum Gb size in order to accommodate the feed.[23]

A User can opt to connect to a Premium NYSE Data Product as a resilient feed or as Feed A or Feed B. Connectivity to the two identical Feeds A and B is only available on the IP network.

The Exchange charges a monthly recurring fee for connectivity to Premium NYSE Data Products. The following table shows the Premium NYSE Data Products and corresponding monthly recurring connectivity fees.

Premium NYSE data product	Feed	Monthly recurring connectivity fee per feed
NYSE Arca Integrated Feed	Feed A, IP network only	$1,500
	Feed B, IP network only	1,500
	Resilient, IP network only	3,000
	Resilient, LCN only	1,500
NYSE Best Quote and Trades (BQT)	Feed A, IP network only	500
	Feed B, IP network only	500
	Resilient, IP network only	1,000
	Resilient, LCN only	500
NYSE Integrated Feed	Feed A, IP network only	1,500
	Feed B, IP network only	1,500
	Resilient, IP network only	3,000
	Resilient, LCN only	1,500
NYSE MKT Integrated Feed	Feed A, IP network only	300
	Feed B, IP network only	300
	Resilient, IP network only	600
	Resilient, LCN only	300

In addition to the connectivity fees, the Exchange proposes to add the following language to its Price List:

Pricing for Premium NYSE Data Products is for connectivity only. Connectivity to Premium NYSE Data Products is subject to any technical provisioning requirements and authorization from the provider of the data feed. Market data fees for the Premium NYSE Data Products are charged by the provider of the data feed. The Exchange is not the exclusive method to connect to Premium NYSE Data Products.

Connectivity to Third Party Systems

The Exchange proposes to revise the Price List to clarify that Users may obtain connectivity to Third Party Systems of multiple third party markets and other content service providers for a fee. Users connect to Third Party Systems over the IP network.[24] The Exchange selects what connectivity to Third Party Systems to offer in the data center based on User demand.

In order to obtain access to a Third Party System, a User enters into an agreement with the relevant third party content service provider, pursuant to which the third party content service provider charges the User for access to the Third Party System. The Exchange then establishes a unicast connection between the User and the relevant third party content service provider over the IP network. The Exchange charges the User for the connectivity to the Third Party System. A User only receives, and is only charged for, access to Third Party Systems for which it enters into agreements with the third party content service provider.

With the exception of the ICE feed,[25] the Exchange has no ownership interest in the Third Party Systems. Establishing a User's access to a Third Party System does not give the Exchange any right to use the Third Party Systems. Connectivity to a Third Party System does not provide access or order entry to the Exchange's execution system, and a User's connection to a Third Party System is not through the Exchange's execution system.[26]

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[21] *See* Securities Exchange Act Release Nos. 44138 (December 7, 2001), 66 FR 64895 (December 14, 2001) (SR–NYSE–2001–42) (establishing fees for NYSE OpenBook); 50844 (December 13, 2004), 69 FR 76806 (December 22, 2004) (SR–NYSE–2004–53) (establishing fee for NYSE Alerts); 59543 (March 9, 2009), 74 FR 11159 (March 16, 2009) (establishing fee for NYSE Order Imbalances); 59290 (January 23, 2009) 74 FR 5707 (January 30, 2009) (SR–NYSE–2009–05) (establishing pilot program for NYSE Trades); and 62181 (May 26, 2010), 75 FR 31488 (June 3, 2010) (SR–NYSE–2010–30) (establishing NYSE BBO). *See also* Securities Exchange Act Release No. 76968 (January 22, 2016), 81 FR 4689 (January 27, 2016) (establishing NYSE Arca Order Imbalances).

[22] As noted above, certification and testing feeds included with a Premium NYSE Data Product are only available over the IP network.

[23] For example, a User connecting to the NYSE Arca Integrated Feed, NYSE Integrated Feed or NYSE MKT Integrated Feed would need a dedicated connection in order to connect to the A Feed or B Feed using a 1 Gb IP network connection. In order to connect to the resilient feeds, the User would require an LCN or IP network connection of at least 10 Gb.

[24] *See* IP Network Release, *supra* note 7, at 7889.

[25] ICE is owned by the Exchange's ultimate parent, Intercontinental Exchange, Inc., and so the Exchange has an indirect interest in the ICE feeds. The ICE feeds include both market data and trading and clearing services, but the Exchange includes it as a Third Party Data Feed. In order for a User to receive an ICE feed, ICE must provide authorization for the User to receive both data and trading and clearing services.

[26] The Exchange has a dedicated network connection to each of the Third Party Systems.

The Exchange charges a monthly recurring fee for connectivity to a Third Party System. Specifically, when a User requests access to a Third Party System, it identifies the applicable third party market or other content service provider and what bandwidth connection it requires.

The monthly recurring fee the Exchange charges Users for unicast connectivity to each Third Party System varies by the bandwidth of the connection, as follows:

Bandwidth of connection to Third Party System	Monthly recurring fee per connection to Third Party System
1Mb	$200
3Mb	400
5Mb	500
10Mb	800
25Mb	1,200
50Mb	1,800
100Mb	2,500
200 Mb	3,000
1 Gb	3,500

The Exchange provides connectivity to the following Third Party Systems:

Americas Trading Group (ATG)
BATS
Boston Options Exchange (BOX)
Chicago Board Options Exchange (CBOE)
Credit Suisse
International Securities Exchange (ISE)
Nasdaq
National Stock Exchange
NYFIX Marketplace

In addition to the connectivity fees, the Exchange proposes to add language to its Price List stating the following:

> Pricing for access to the execution systems of third party markets and other service providers (Third Party Systems) is for connectivity only. Connectivity to Third Party Systems is subject to any technical provisioning requirements and authorization from the provider of the data feed. Connectivity to Third Party Systems is over the IP network. Any applicable fees are charged independently by the relevant third party content service provider. The Exchange is not the exclusive method to connect to Third Party Systems.

Connectivity to Third Party Data Feeds

The Exchange proposes to revise the Price List to clarify that Users may obtain connectivity to Third Party Data Feeds for a fee. The Exchange receives Third Party Data Feeds from multiple national securities exchanges and other content service providers at its data center. It then provides connectivity to that data to Users for a fee. With the exceptions of Global OTC and NYSE Global Index, Users connect to Third Party Data Feeds over the IP network.[27]

The Exchange notes that charging Users a monthly fee for connectivity to Third Party Data Feeds is consistent with the monthly fee Nasdaq charges its co-location customers for connectivity to third party data. For instance, Nasdaq charges its co-location customers monthly fees of $1,500 and $4,000 for connectivity to BATS Y and BATS, respectively, and of $2,500 for connectivity to EDGA or EDGX.[28]

In order to connect to a Third Party Data Feed, a User enters into a contract with the relevant third party market or other content service provider, pursuant to which the content service provider charges the User for the Third Party Data Feed. The Exchange receives the Third Party Data Feed over its fiber optic network and, after the data provider and User enter into the contract and the Exchange receives authorization from the data provider, the Exchange re-transmits the data to the User over the User's port. The Exchange charges the User for the connectivity to the Third Party Data Feed. A User only receives, and is only charged for, connectivity to the Third Party Data Feeds for which it enters into contracts.

With the exception of the Intercontinental Exchange ("ICE"), Global OTC and NYSE Global Index feeds,[29] the Exchange has no affiliation with the sellers of the Third Party Data Feeds. It has no right to use the Third Party Data Feeds other than as a redistributor of the data. The Third Party Data Feeds do not provide access or order entry to the Exchange's execution system. With the exception of the ICE feeds, the Third Party Data Feeds do not provide access or order entry to the execution systems of the third party generating the feed.[30] The Exchange receives Third Party Data Feeds via arms-length agreements and it has no inherent advantage over any other distributor of such data.

The Exchange charges a monthly recurring fee for connectivity to each Third Party Data Feed. The monthly recurring fee is per Third Party Data Feed, with the exception that the monthly recurring feed for SuperFeed and MSCI varies by the bandwidth of the connection. Depending on its needs and bandwidth, a User may opt to receive all or some of the feeds or services included in a Third Party Data Feed.

The following table shows the feeds that connectivity to each Third Party Data Feed provides, together with the applicable monthly recurring fee.

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[27] *See* IP Network Release, *supra* note 7, at 7889. Users can connect to Global OTC and NYSE Global Index over the IP network or LCN.

[28] *See* Nasdaq Stock Market Rule 7034.

[29] ICE and the Global OTC alternative trading system are both owned by the Exchange's ultimate parent, Intercontinental Exchange, Inc., and so the Exchange has an indirect interest in the ICE and Global OTC feeds. The NYSE Global Index feed includes index and exchange traded product valuations data, with data drawn from the Exchange, the Affiliate SROs, and third party exchanges. Because it includes third party data, the NYSE Global Index feed is considered a Third Party Data Feed. As with all Third Party Data Feeds, the Exchange is not the exclusive method to connect to the ICE, Global OTC or NYSE Global Index feeds.

[30] Unlike other Third Party Data Feeds, the ICE feeds include both market data and trading and clearing services. In order to receive the ICE feeds, a User must receive authorization from ICE to receive both market data and trading and clearing services.

Third party data feed	Monthly recurring connectivity fee per third party data feed
Bats BZX Exchange (BZX) and Bats BYX Exchange (BYX)	$2,000
Bats EDGX Exchange (EDGX) and Bats EDGA Exchange (EDGA)	2,000
Chicago Board Options Exchange (CBOE)	2,000
Chicago Stock Exchange (CHX)	400
Euronext	600
Financial Industry Regulatory Authority (FINRA)	500
Global OTC	100
Intercontinental Exchange (ICE)	1,500
Montréal Exchange (MX)	1,000
MSCI 5 Mb	500
MSCI 20 Mb	2,000
NASDAQ Stock Market	2,000
NASDAQ OMX Global Index Data Service	100
NASDAQ OMDF	100
NASDAQ UQDF & UTDF	500
NYSE Global Index	100
OTC Markets Group	1,000
SR Labs—SuperFeed ≤ 500 Mb	250
SR Labs—SuperFeed >500 Mb to ≤ 1.25 Gb	800
SR Labs—SuperFeed >1.25 Gb	1,000
TMX Group	2,500

In addition to the above connectivity fees, the Exchange proposes to add the following language to its Price List:

> Pricing for data feeds from third party markets and other content service providers (Third Party Data Feeds) is for connectivity only. Connectivity to Third Party Data Feeds is subject to any technical provisioning requirements and authorization from the provider of the data feed. Connectivity to Third Party Data Feeds is over the IP network, with the exception that Users can connect to Global OTC and NYSE Global Index over the IP network or LCN. Market data fees are charged independently by the relevant third party market or content service provider. The Exchange is not the exclusive method to connect to Third Party Data Feeds.

Third Party Data Feed providers may charge redistribution fees, such as Nasdaq's Extranet Access Fees and OTC Markets Group's Access Fees.[31] When the Exchange receives a redistribution fee, it passes through the charge to the User, without change to the fee. The fee is labeled as a pass-through of a redistribution fee on the User's invoice. The Exchange proposes to add language to the Price List accordingly.

The Exchange provides third party markets or content providers that are also Users connectivity to their own Third Party Data Feeds. The Exchange does not charge Users that are third party markets or content providers for connectivity to their own feeds, as in the Exchange's experience such parties generally receive their own feeds for purposes of diagnostics and testing. The Exchange proposes to add language to the Price List accordingly.

Connectivity to Third Party Testing and Certification Feeds

The Exchange offers Users connectivity to third party certification and testing feeds. Certification feeds are used to certify that a User conforms to any of the relevant content service provider's requirements for accessing Third Party Systems or receiving Third Party Data, while testing feeds provide Users an environment in which to conduct tests with non-live data.[32] Such feeds, which are solely used for certification and testing and do not carry live production data, are available over the IP network.

The Exchange proposes to revise the Price List to include connectivity to third party certification and testing feeds. The Exchange charges a connectivity fee of $100 per month per feed.

The Exchange proposes to add the following connectivity fees and language to its Price List:

Connectivity to third party certification and testing feeds.	$100 monthly recurring fee per feed

The Exchange provides connectivity to third party testing and certification feeds provided by third party markets and other content service providers. Pricing for third party testing and certification feeds is for connectivity only. Connectivity to third party testing and certification feeds is subject to any technical provisioning requirements and authorization from the provider of the data feed. Connectivity to third party testing and certification feeds is over the IP network. Any applicable fees are charged independently by the relevant third party market or content service provider. The Exchange is not the exclusive method to connect to third party testing and certification feeds.

Connectivity to DTCC

The Exchange provides Users connectivity to DTCC for clearing, fund transfer, insurance, and settlement services.[33] The Exchange proposes to revise the Price List to include connectivity to DTCC. The Exchange charges a connectivity fee of $500 per month for connections to DTCC of 5 Mb and $2,500 for connections of 50 Mb. Connectivity to DTCC is available over the IP network.

In order to connect to DTCC, a User enters into a contract with DTCC, pursuant to which DTCC charges the User for the services provided. The

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[31] *See* NASDAQ Stock Market LLC Rule 7025, "Extranet Access Fee", and OTC Markets Market Data Distribution Agreement Appendix B, "Fees" at *http://www.otcmarkets.com/content/doc/market-data-fees-2016.pdf. See also* Securities Exchange Act Release No. 74040 (January 13, 2015), 80 FR 2460 (January 16, 2015) (SR–NASDAQ–2015–003).

[32] For example, a User that trades on a third party exchange may wish to test the exchange's upcoming releases and product releases or may wish to test a new algorithm in a testing environment prior to making it live.

[33] Such connectivity to DTCC is distinct from the access to shared data services for clearing and settlement services that a User receives when it purchases access to the LCN or IP network. The shared data services allow Users and other entities with access to the Trading Systems to post files for settlement and clearing services to access.

Exchange receives the DTCC feed over its fiber optic network and, after DTCC and the User enter into the services contract and the Exchange receives authorization from DTCC, the Exchange provides connectivity to DTCC to the User over the User's IP network port. The Exchange charges the User for the connectivity to DTCC.

Connectivity to DTCC does not provide access or order entry to the Exchange's execution system, and a User's connection to DTCC is not through the Exchange's execution system.

The Exchange proposes to add the following connectivity fees and language to its Price List:

5 Mb connection to DTCC.	$500 monthly recurring fee
50 Mb connection to DTCC.	$2,500 monthly recurring fee

Pricing for connectivity to DTCC feeds is for connectivity only. Connectivity to DTCC feeds is subject to any technical provisioning requirements and authorization from DTCC. Connectivity to DTCC feeds is over the IP network. Any applicable fees are charged independently by DTCC. The Exchange is not the exclusive method to connect to DTCC feeds.

Virtual Control Circuits

Finally, the Exchange proposes to revise the Price List to offer VCCs between two Users. VCCs are connections between two points over dedicated bandwidth using the IP network. A VCC (previously called a "peer to peer" connection) is a two-way connection which the two participants can use for any purpose.

The Exchange bills the User requesting the VCC, but will not set up a VCC until the other User confirms that it wishes to have the VCC set up.

The Exchange proposes to revise the Price List to include VCCs between two Users. The fee for VCCs is based on the bandwidth utilized, as follows:

Type of service	Description	Amount of charge
Virtual Control Circuit between two Users	1Mb	$200 monthly charge.
	3Mb	$400 monthly charge.
	5Mb	$500 monthly charge.
	10Mb	$800 monthly charge.
	25Mb	$1,200 monthly charge.
	50Mb	$1,800 monthly charge.
	100Mb	$2,500 monthly charge.

General

As is the case with all Exchange co-location arrangements, (i) neither a User nor any of the User's customers would be permitted to submit orders directly to the Exchange unless such User or customer is a member organization, a Sponsored Participant or an agent thereof (*e.g.*, a service bureau providing order entry services); (ii) use of the co-location services proposed herein would be completely voluntary and available to all Users on a non-discriminatory basis;[34] and (iii) a User would only incur one charge for the particular co-location service described herein, regardless of whether the User connects only to the Exchange or to the Exchange and one or both of its Affiliate SROs.[35]

The proposed change is not otherwise intended to address any other issues relating to co-location services and/or related fees, and the Exchange is not aware of any problems that Users would have in complying with the proposed change.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[36] in general, and furthers the objectives of sections 6(b)(5) of the Act,[37] in particular, because it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities, to remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, to protect investors and the public interest and because it is not designed to permit unfair discrimination between customers, issuers, brokers, or dealers.

The Exchange believes that the proposed changes remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because a User is provided choices with respect to its Access and Connectivity, helping it tailor its data center operations to the requirements of its business operations by allowing it to select the form and latency of connectivity that best suits its needs. The Exchange provides the Access and Connectivity as conveniences to Users. Use of Access or Connectivity is completely voluntary, and is one of several connectivity options available to a User. As alternatives to using the Access and Connectivity provided by the Exchange, a User may access or connect to such services and products through another User or through a connection to an Exchange access center outside the data center, third party access center, or third party vendor. The User may make such connection through a third party telecommunication provider, third party wireless network, the SFTI network, or a combination thereof.

The Exchange believes that revising the Price List to provide a more detailed description of the access to the Exchange Systems and connectivity to Included Data Products that Users are provided with their purchase of access to the LCN or IP network would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the proposed changes would make the descriptions of access to the LCN and IP network more accessible and transparent, thereby providing market participants with clarity as to what connectivity is included in the purchase of access to the LCN and IP network.

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[34] As is currently the case, Users that receive co-location services from the Exchange will not receive any means of access to the Exchange's trading and execution systems that is separate from, or superior to, that of other Users. In this regard, all orders sent to the Exchange enter the Exchange's trading and execution systems through the same order gateway, regardless of whether the sender is co-located in the data center or not. In addition, co-located Users do not receive any market data or data service product that is not available to all Users, although Users that receive co-location services normally would expect reduced latencies in sending orders to, and receiving market data from, the Exchange.

[35] *See* SR–NYSE–2013–59, *supra* note 5 at 51766. The Affiliate SROs have also submitted substantially the same proposed rule change to propose the changes described herein. *See* SR–NYSEMKT–2016–63 and SR–NYSEArca-2016–89.

[36] 15 U.S.C. 78f(b).

[37] 15 U.S.C. 78f(b)(5).

The Exchange believes that providing a more detailed description of the access to Third Party Systems and related fees, as well as the connectivity and related fees for Premium NYSE Data Products, Third Party Data Feeds, third party testing and certification feeds and DTCC, would remove impediments to, and perfect the mechanisms of, a free and open market and a national market system and, in general, protect investors and the public interest because the proposed changes would make the descriptions of market participants' connectivity options more accessible and transparent, thereby providing market participants with clarity as to what options for connectivity are available to them and what the related costs are.

In addition, the Exchange believes that providing connectivity to third party testing and certification feeds removes impediments to, and perfects the mechanisms of, a free and open market and a national market system and, in general, protects investors and the public interest because such feeds provide Users an environment in which to conduct tests with non-live data, including testing for upcoming releases and product enhancements or the User's own software development, and allow Users to certify conformance to any applicable technical requirements. Similarly, the Exchange believes that providing connectivity to DTCC removes impediments to, and perfects the mechanisms of, a free and open market and a national market system and, in general, protects investors and the public interest because it provides efficient connection to clearing, fund transfer, insurance, and settlement services.

The Exchange believes that providing Users with VCCs removes impediments to, and perfects the mechanisms of, a free and open market and a national market system because VCCs provide each User with an additional option for connectivity to another User, helping it tailor its data center operations to the requirements of its business operations by allowing it to select the form of connectivity that best suits its needs. The Exchange provides VCCs as a convenience to Users. Use of a VCC is completely voluntary. As an alternative to an Exchange-provided VCC, a User may connect to another User through a cross connect.

The Exchange also believes that the proposed rule change is consistent with section 6(b)(4) of the Act,[38] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

The Exchange believes that the proposed fees changes are consistent with section 6(b)(4) of the Act for multiple reasons. The Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange.

The Exchange believes that the services and fees proposed herein are equitably allocated and not unfairly discriminatory because, in addition to the services being completely voluntary, they are available to all Users on an equal basis (*i.e.,* the same products and services are available to all Users). All Users that voluntarily select to access the Exchange Systems or connect to Included Data Products would not be subject to a charge above and beyond the fee paid for the relevant LCN or IP network access. All Users that voluntarily select to receive access to Third Party Systems, connectivity to Premium NYSE Data Products, Third Party Data Feeds, third party testing and certification feeds and DTCC, or a VCC would be charged the same amount for the same services.

The Exchange believes that the services and fees proposed herein are reasonable, equitably allocated and not unfairly discriminatory because the Exchange provides Access and Connectivity as conveniences to Users. Use of Access or Connectivity is completely voluntary, and is one of several connectivity options available to a User. As alternatives to using the Access and Connectivity provided by the Exchange, a User may access or connect to such services and products through another User or through a connection to an Exchange access center outside the data center, third party access center, or third party vendor. The User may make such connection through a third party telecommunication provider, third party wireless network, the SFTI network, or a combination thereof. Users that opt to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the relevant market or content provider may receive access or connectivity. Similarly, the Exchange provides VCCs between Users as a convenience to Users. Use of a VCC is completely voluntary. As an alternative to an Exchange-provided VCC, a User may connect to another User through a cross connect.

Overall, the Exchange believes that the proposed charges are reasonable, equitably allocated and not unfairly discriminatory because the Exchange offers Access, Connectivity, and VCCs as conveniences to Users, and in doing so incurs certain costs. The expenses incurred and resources expended by the Exchange generally include costs related to the data center facility hardware and technology infrastructure; maintenance and operational costs, such as the costs of responding to any production issues; and the costs related to the personnel required for initial installation and administration, monitoring, support and maintenance of such services. Since the inception of co-location, the Exchange has made numerous improvements to the network hardware and technology infrastructure and has established additional administrative controls. The Exchange has expanded the network infrastructure to keep pace with the increased number of services available to Users, including the increasing bandwidth required for Access and Connectivity, including resilient and redundant feeds. For example, the Exchange must ensure that the network infrastructure has the necessary bandwidth for the Included Data Products as well as the Premium NYSE Data Products, which generally require greater bandwidth. In addition, the Exchange incurs certain costs specific to providing connectivity to Third Party Data Feeds, Third Party Systems, third party testing and certification feeds and

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[38] 15 U.S.C. 78f(b)(4).

DTCC, including the costs of maintaining multiple connections to each Third Party Data Feed, Third Party System, and DTCC, allowing the Exchange to provide resilient and redundant connections; adapting to any changes made by the relevant third party; and covering any applicable fees (other than redistribution fees) charged by the relevant third party, such as port fees.

Co-location was created to permit Users "to rent space on premises controlled by the Exchange in order that they may locate their electronic servers in close physical proximity to the Exchange's trading and execution systems."[39] The expectation was that normally Users sending orders to the Exchange would have reduced latencies.[40] Accordingly, the Exchange believes that including access to the Exchange Systems with the purchase of access to the LCN or IP network is reasonable because such access is directly related to the purpose of co-location.

The Exchange believes that including connectivity to the Included Data products with the purchase of access to the LCN or IP network is reasonable and not unfairly discriminatory because Users are not required to use any of their bandwidth to access Exchange Systems or connect to an Included Data Product unless they wish to do so. Rather, a User only receives access to the Exchange Systems and connectivity to the Included Data Products that it selects, and a User can change which of such access or connections it receives at any time, subject to authorization from the data provider or relevant Exchange or Affiliate SRO. Including connectivity to the Included Data products with the purchase of access to the LCN or IP network is a commercial decision. As noted above, the Exchange operates in a highly competitive market. If a particular exchange charges excessive fees for co-location services—such as excessive fees for access to the local area network within the exchange's colocation space—affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies. The Exchange believes that including connectivity to Included Data Products with the purchase of access to the LCN or IP network is consistent with Nasdaq's colocation service, which, apart from an installation fee, does not charge its co-located customers for connectivity to Nasdaq data.[41]

The Exchange believes that its fees for connectivity to Premium NYSE Data Products are reasonable because they allow the Exchange to defray or cover the costs associated with offering Users connectivity to Premium NYSE Data Products while providing Users the benefit of reduced latency when connecting to data feeds that integrate, or include data elements from, several Included Data Products. Charging separate connectivity fees for Premium NYSE Data Products is a commercial decision. As noted above, the Exchange operates in a highly competitive market. If a particular exchange charges excessive fees for co-location services—such as excessive fees for connectivity to the exchange's market data—affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies. Although Nasdaq does not include connectivity to any of the Premium NYSE Data Products in its co-location services, the Exchange believes that the proposed fees are generally consistent with the fees that a Nasdaq co-location customer would pay for connectivity to the individual feeds included in a Premium NYSE Data Product. For example, the NYSE Integrated Feed includes, among other things, information available from three of the Included Data Products: NYSE OpenBook, NYSE Trades, and NYSE Order Imbalances. Nasdaq offers connectivity to two of those feeds, OpenBook Ultra and NYSE Trades, for which it would charge a co-located customer a combined monthly fee of $2,600.[42] The Exchange believes that it is reasonable to charge less for connectivity to the resilient Premium NYSE Data Products on the LCN than over the IP network, because Users do not have the option to connect to the A or B Feed over the LCN.

The Exchange believes that charging separate connectivity fees for Third Party Data Feeds and access to Third Party Systems, third party testing and certification feeds and connectivity to DTCC is reasonable and not unfairly discriminatory because, in the Exchange's experience, not all Users connect to Third Party Data Feeds, Third Party Systems, third party testing and certification feeds or DTCC. By charging only those Users that receive such connectivity, only the Users that directly benefit from it support its cost.

The Exchange believes the fees for connectivity to Third Party Data Feeds are reasonable because they allow the Exchange to defray or cover the costs associated with offering Users connectivity to Third Party Data Feeds while providing Users the convenience of receiving such Third Party Data Feeds within co-location, helping them tailor their data center operations to the requirements of their business operations by allowing them to select the form and latency of connectivity that best suits their needs. The Exchange believes that its proposed charges for connectivity to Third Party Data Feeds are similar to the connectivity fees Nasdaq imposes on its co-location customers. For instance, Nasdaq charges its co-location customers monthly fees of $1,500 and $4,000 for connectivity to BATS Y and BATS, respectively, and of $2,500 for connectivity to EDGA or EDGX.[43]

The Exchange believes that its connectivity fees for access to Third Party Systems are reasonable because they allow the Exchange to defray or cover the costs associated with offering such access while providing Users the convenience of being able to access such Third Party Systems, helping them tailor their data center operations to the requirements of their business operations by allowing them to select the form and latency of connectivity that best suits their needs. Similarly, the Exchange believes that its fees for connectivity to DTCC are reasonable because they allow the Exchange to defray or cover the costs associated with offering such access while providing Users the benefit of an efficient connection to clearing, fund transfer, insurance, and settlement services. The Exchange further believes the fees for connectivity to Third Party Systems and DTCC are reasonable because the monthly recurring fee the Exchange charges Users for connectivity to each Third Party System and DTCC varies by the bandwidth of the connection, and so is generally proportional to the bandwidth required.

The Exchange also believes that its connectivity fees for access to third party testing and certification feeds are reasonable because they allow the Exchange to defray or cover the costs associated with offering such access while providing Users the benefit of having an environment in which to conduct tests with non-live data, including testing for upcoming releases and product enhancements or the User's own software development, and to certify conformance to any applicable technical requirements.

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[39] Original Co-Location Filing, *supra* note 4, at 59310.

[40] *Id.*, at 59311.

[41] *See* Nasdaq Stock Market Rule 7034.

[42] *Id.*

[43] *See* Nasdaq Stock Market Rule 7034.

The Exchange believes it is reasonable that redistribution fees charged by providers of Third Party Data Feeds are passed through to the User, without change to the fee. If not passed through, the cost of the re-distribution fees would be factored into the proposed fees for connectivity to Third Party Data Feeds. The Exchange believes that passing through the fees makes them more transparent to the User, allowing the User to better assess the cost of the connectivity to a Third Party Data Feed by seeing the individual components of the cost, *i.e.* the Exchange's fee and the redistribution fee.

The Exchange believes that it is reasonable that it does not charge third party markets or content providers for connectivity to their own Third Party Data Feeds, as in the Exchange's experience such parties generally receive their own feeds for purposes of diagnostics and testing. The Exchange believes that it removes impediments to, and perfects the mechanisms of, a free and open market and a national market system and, in general, protects investors and the public interest to facilitate such diagnostics and testing.

Finally, the Exchange also believes that its fees for VCCs between two Users are reasonable because they allow the Exchange to defray or cover the costs associated with offering such VCCs while providing Users the benefit of an additional option for connectivity to another User, helping them tailor their data center operations to the requirements of their business operations by allowing them to select the form of connectivity that best suits their needs. As an alternative to an Exchange-provided VCC, a User may connect to another User through a cross connect.

For the reasons above, the proposed changes do not unfairly discriminate between or among market participants that are otherwise capable of satisfying any applicable co-location fees, requirements, terms and conditions established from time to time by the Exchange.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act,[44] the Exchange believes that the proposed rule change will not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because, in addition to the proposed services being completely voluntary, they are available to all Users on an equal basis (*i.e.* the same products and services are available to all Users).

The Exchange believes that providing Users with access to the Exchange Systems and Third Party Systems and connectivity to NYSE Data Products, Third Party Data Feeds, third party testing and certification feeds, and DTCC does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because such Access and Connectivity satisfies User demand for access and connectivity options, and several other access and connectivity options are available to a User. As alternatives to using the Access and Connectivity provided by the Exchange, a User may access or connect to such services and products through another User or through a connection to an Exchange access center outside the data center, third party access center, or third party vendor. The User may make such connection through a third party telecommunication provider, third party wireless network, the SFTI network, or a combination thereof. Users that opt to use Access or Connectivity would not receive access or connectivity that is not available to all Users, as all market participants that contract with the relevant market or content provider may receive access or connectivity. In this way, the proposed changes would enhance competition by helping Users tailor their Access and Connectivity to the needs of their business operations by allowing them to select the form and latency of access and connectivity that best suits their needs.

Similarly, the Exchange believes that providing VCCs between Users does not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act because providing VCCs satisfies User demand for an alternative to cross connects.

The Exchange believes that revising the Price List to provide a more detailed description of the Access and Connectivity available to Users would make such descriptions more accessible and transparent, thereby providing market participants with clarity as to what Access and Connectivity is available to them and what the related costs are, thereby enhancing competition by ensuring that all Users have access to the same information regarding Access and Connectivity.

Finally, the Exchange operates in a highly competitive market in which exchanges offer co-location services as a means to facilitate the trading and other market activities of those market participants who believe that co-location enhances the efficiency of their operations. Accordingly, fees charged for co-location services are constrained by the active competition for the order flow of, and other business from, such market participants. If a particular exchange charges excessive fees for co-location services, affected market participants will opt to terminate their co-location arrangements with that exchange, and adopt a possible range of alternative strategies, including placing their servers in a physically proximate location outside the exchange's data center (which could be a competing exchange), or pursuing strategies less dependent upon the lower exchange-to-participant latency associated with co-location. Accordingly, the exchange charging excessive fees would stand to lose not only co-location revenues but also the liquidity of the formerly co-located trading firms, which could have additional follow-on effects on the market share and revenue of the affected exchange. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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[44] 15 U.S.C. 78f(b)(8).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File No. SR–NYSE–2016–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File No. SR–NYSE–2016–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File No. SR–NYSE–2016–45, and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[45]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19586 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

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[45] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78548; File No. SR–NYSEMKT–2016–74]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing and Immediate Effectiveness of Proposed Change To Modify the NYSE Amex Options Fee Schedule

August 11, 2016.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 1, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to modify the NYSE Amex Options Fee Schedule ("Fee Schedule"). The Exchange proposes to implement the fee change effective August 1, 2016. The proposed change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The purpose of this filing is to amend section I. A. of the Fee Schedule to adjust certain Marketing Charges for Electronic Executions in standard options contracts, effective on August 1, 2016.[4]

The Exchange assesses a Marketing Charge to all NYSE Amex Options Market Makers, which includes Specialists, e-Specialists and Directed Order Market Makers (collectively, "Market Makers") for contracts they execute Electronically when the contra-party to the execution is a Customer.[5] Currently, the Exchange collects a Marketing Charge from Market Makers of $0.25 per contract in Penny Pilot Issues, and $0.65 per contract on in non-Penny Pilot Issues.[6] The Exchange proposes to modify the Marketing Charge for transactions in non-Penny Pilot Issues to $0.70 per contract, which is comparable to the marketing fees charged by competing options exchanges.[7]

The Exchange also proposes to correct certain typographical errors in Note 3 to section I.A. of the Fee Schedule, which would add clarity and transparency to the Fee Schedule.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[8] in general, and furthers the objectives of sections 6(b)(4) and (5) of the Act,[9] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] *See* Fee Schedule, section I. A. (Rates for Standard Options Transactions), *available here, https://www.nyse.com/publicdocs/nyse/markets/amex-options/NYSE_Amex_Options_Fee_Schedule.pdf.*

[5] As specified in the Fee Schedule, the Exchange acts as an administrator in collecting and re-distributing all monies collected from the Marketing Charges. *See id.,* Note 3 to Section I. A.

[6] The term "non-Penny Pilot Issues" applies to those option issues that are not in the Penny Pilot pursuant to Rule 960NY, Commentary .02.

[7] *See, e.g.,* Chicago Board Options Exchange ("CBOE") fee schedule, *available here, http://www.cboe.com/publish/feeschedule/CBOEFeeSchedule.pdf (charging a marketing fee of $0.70 per contract for non-Penny Pilot Issues);* Nasdaq OMX PHLX ("PHLX") fee schedule, *available here, http://www.nasdaqtrader.com/Micro.aspx?id=phlxpricing (same).*

[8] 15 U.S.C. 78f(b).

[9] 15 U.S.C. 78f(b)(4) and (5).

The Exchange notes that the U.S. options markets are highly competitive, and the Marketing Charge is intended to provide an incentive for order flow providers ("OFPs") to route Customer orders to the Exchange. To the extent the proposed fees permit the Exchange to continue to attract greater volume and liquidity, the proposed change would also strengthen the Exchange's market quality for all market participants.

The Exchange also believes that its proposed increase to the Marketing Charge for Non-Penny Pilot Issues is reasonable and not unfairly discriminatory since it is the same as the amount charged by competing options exchanges for Non-Penny Pilot Issues.[10]

The Exchange believes the correction of certain typographical errors in Note 3 to section I.A. of the Fee Schedule are reasonable because the corrections would add clarity and transparency to the Fee Schedule.

For these reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act,[11] the Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange believes the proposed increase in certain Marketing Charges are pro-competitive as the proposed increased allows the Exchange to fund a program that competes on an equal basis with programs on other exchanges,[12] and may encourage OFPs to direct Customer order flow to the Exchange and any resulting increase in volume and liquidity to the Exchange would benefit all Exchange participants through increased opportunities to trade as well as enhancing price discovery.

The Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues. In such an environment, the Exchange must continually review, and consider adjusting, its fees and credits to remain competitive with other exchanges. For the reasons described above, the Exchange believes that the proposed rule change reflects this competitive environment.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)[13] of the Act and subparagraph (f)(2) of Rule 19b–4[14] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)[15] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEMKT–2016–74 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–74. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–74 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[16]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19579 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78553; File No. SR–FINRA–2016–030]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of a Proposed Rule Change Amending Rule 12504 of the Code of Arbitration Procedure for Customer Disputes and Rule 13504 of the Code of Arbitration Procedure for Industry Disputes Relating to Motions To Dismiss in Arbitration

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission

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[10] *See supra* note 7.

[11] 15 U.S.C. 78f(b)(8).

[12] *See supra* note 7.

[13] 15 U.S.C. 78s(b)(3)(A).

[14] 17 CFR 240.19b–4(f)(2).

[15] 15 U.S.C. 78s(b)(2)(B).

[16] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

("Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by FINRA. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

FINRA is proposing to amend FINRA Rule 12504 of the Code of Arbitration Procedure for Customer Disputes ("Customer Code") and FINRA Rule 13504 of the Code of Arbitration Procedure for Industry Disputes ("Industry Code," and together with the Customer Code, the "Codes"), to provide that arbitrators may act upon a motion to dismiss a party or claim prior to the conclusion of a party's case in chief if the arbitrators determine that the non-moving party previously brought a claim regarding the same dispute against the same party, and the dispute was fully and finally adjudicated on the merits and memorialized in an order, judgment, award, or decision.

The text of the proposed rule change is available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, FINRA included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. FINRA has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

Background

In 2009, FINRA amended the Codes to adopt new FINRA Rules 12504 and 13504 (Motions to Dismiss), and to amend FINRA Rules 12206 and 13206 (Time Limits), to establish procedures limiting motions to dismiss in arbitration.[3] A motion to dismiss is a request made to the arbitrators to remove a party or some or all claims raised by a party filing a claim. If the arbitrators grant a motion to dismiss before a hearing is held (a prehearing motion), the party bringing the claim loses the opportunity to have his or her arbitration case heard in whole or in part by the arbitrators. FINRA limited motions to dismiss because FINRA believed that respondents were filing prehearing motions routinely and repetitively in an effort to delay scheduled hearing sessions on the merits, increase investors' costs, and intimidate less sophisticated investors.

The procedures set forth in the Codes significantly limit the use of motions to dismiss. Among other requirements, FINRA requires parties to file prehearing motions to dismiss in writing, separately from the answer, and only after they file the answer. The full panel of arbitrators must decide a motion to dismiss, and the panel must hold a hearing on the motion unless the parties waive the hearing. If a panel grants a motion to dismiss, the decision must be unanimous, and must be accompanied by a written explanation.

Under the Codes, arbitrators cannot act upon a motion prior to the conclusion of the non-moving party's case in chief unless the arbitrators determine that: (1) The non-moving party previously released the claim in dispute by a signed settlement or written release, (2) the moving party was not associated with the account, security, or conduct at issue,[4] or (3) a claim is not eligible for arbitration because it does not meet the six-year time limit for submitting a claim.[5]

Furthermore, the procedures set forth in the Codes impose stringent sanctions against parties for engaging in abusive practices. For instance, under the motions to dismiss rules, if the arbitrators deny a motion to dismiss prior to the conclusion of the non-moving party's case in chief, the arbitrators must assess forum fees associated with hearing the motion against the moving party, and if they find the motion to be frivolous, they must award reasonable costs and attorneys' fees to a party that opposed the motion. Moreover, the arbitrators may issue other sanctions under the Codes if they determine that a party filed a motion under the rule in bad faith.[6]

FINRA Dispute Resolution Task Force

In 2014, FINRA formed the FINRA Dispute Resolution Task Force ("Task Force") to suggest strategies to enhance the transparency, impartiality, and efficiency of FINRA's securities dispute resolution forum for all participants. The Task Force reviewed the topic of motions to dismiss and determined that the rule appears to be working as intended to prevent frivolous motions to dismiss. However, the Task Force reached a consensus that in instances where arbitrations involve claims previously adjudicated by a court or arbitrated by an arbitration panel, respondents should be able to seek early dismissal. The Task Force recommended that FINRA amend the motions to dismiss rule in customer cases to include one additional category for which motions to dismiss may be made before the conclusion of the case in chief: situations where the dispute was previously concluded through adjudication or arbitration and memorialized in an order, judgment, award, or decision.

Proposed Rule Change

FINRA agrees with the Task Force recommendation, and believes that it would be appropriate to add the additional ground for arbitrators to act on motions to dismiss prior to the conclusion of the claimant's case in chief in both customer and industry cases. Currently under the Codes, the Director of Arbitration can deny use of the forum for customer and industry claims if it is clear that a party is bringing exactly the same claims against the same parties that were already heard at the forum.[7] However, if there are questions about whether the matter concerns a different claim, the Director is likely to deny the motion and allow the arbitration to proceed so that the arbitrators can decide the merits of the parties' assertions. FINRA believes that adding the additional ground for arbitrators to act on motions to dismiss is appropriate because parties should not be subject to the legal fees associated with arbitrating claims that have been fully adjudicated in a prior proceeding. The proposed rule change would also act as a deterrent to using repeated filings as a means of leverage during settlement negotiations.

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[3] *See Regulatory Notice* 09–07 announcing Commission approval of new FINRA Rules 12504 and 13504 (Motions to Dismiss) and amendments to FINRA Rules 12206 and 13206 (Time Limits).

[4] *See* FINRA Rules 12504 and 13504 (Motions to Dismiss).

[5] *See* FINRA Rules 12206 and 13206 (Time Limits), which provide that no claim shall be eligible for submission to arbitration where six years have elapsed from the occurrence or event giving rise to the claim.

[6] *See* FINRA Rules 12212 and 13212 (Sanctions) relating to available sanctions.

[7] *See* FINRA Rules 12203 and 13303 (Denial of the Forum), which provide that the Director may decline to permit the use of the FINRA arbitration forum if the Director determines that, given the purposes of FINRA and the intent of the Code, the subject matter of the dispute is inappropriate. The Director rarely invokes this authority.

FINRA is proposing to amend FINRA Rules 12504(a)(6) and 13504(a)(6) to add new paragraph (c) which would specify that arbitrators can also act upon a motion to dismiss a party or claim if they determine that the non-moving party previously brought a claim regarding the same dispute[8] against the same party that was fully and finally adjudicated on the merits and memorialized in an order, judgment, award, or decision. The proposed rule change would allow the arbitrators to grant a motion to dismiss relating to a particular controversy if they believe the matter was adjudicated fully even in instances where a claimant adds a new cause of action, or adds additional facts. For example, consider a case where a claimant initiated a claim against a firm for $150,000 for suitability based on a broker's investment in XYZ stock. The arbitrators dismiss the claim after a full hearing. The proposed rule change would allow the arbitrators to hear a motion to dismiss if the claimant subsequently files an arbitration against the same firm relating to the investment in XYZ but in the new case the claimant alleges fraud in inducing the claimant to make the purchase.

2. Statutory Basis

FINRA believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[9] which requires, among other things, that FINRA rules must be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest. FINRA believes that the proposed rule change would enhance efficiency for forum participants because arbitrators would be permitted to dismiss previously adjudicated cases at an earlier point in an arbitration proceeding.

B. Self-Regulatory Organization's Statement on Burden on Competition

FINRA does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Currently, the Codes impose significant restrictions on motions to dismiss an arbitration. With limited exceptions, in cases where the dispute has been permitted to go forward by the Director of Arbitration and a party puts forward a motion to dismiss, arbitrators cannot act upon the motion prior to the conclusion of the non-moving party's case in chief. Both sides incur additional costs related to making and defending the motion. However, a successful motion to dismiss could end part or all of the case resulting in reduced costs for parties.

The Task Force reviewed arbitration case data from 2013 and 2014. During that time period, the Office of Dispute Resolution (ODR) had an average pending caseload of approximately 5,000 cases. ODR recorded 725 cases (both customer and industry disputes) in which a prehearing motion to dismiss was filed by respondents. Of the 725 cases, 249 were still pending at the time of the Task Force review, 310 settled or closed for other reasons prior to any decision on the motion (*i.e.,* bankruptcy, etc.), and 166 closed by award. FINRA reviewed the 166 cases closed by award to determine the arbitrators' decisions regarding a motion to dismiss. The arbitrators granted a prehearing motion to dismiss (in whole or part) in 64 of the 166 cases closed by award. In addition, arbitrators granted a respondent's motion to dismiss *after* the conclusion of claimant's case in chief in 12 of the 166 cases closed by award. These figures suggest that motions to dismiss occur in a small but significant number of cases.

Where arbitrators have sufficient information to determine the finding with respect to the motion to dismiss prior to hearing the non-moving party's case, the proposed rule change will reduce both parties' costs where the motion is granted. Where the motion is denied, the proposed rule change may impose some costs on the non-moving party due to the potential delay and the need to argue the dispute associated with the motion prehearing. FINRA expects the costs to be limited because hearings on narrow issues such as a single motion are generally completed quickly. The rule would continue to permit the non-moving party to present evidence and testimony to the arbitrators concerning the merits of the motion prior to the decision on the motion, and thus would limit the risk that the arbitrators might act on incomplete or insufficient information.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) by order approve or disapprove such proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–FINRA–2016–030 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–030. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10 a.m. and 3 p.m. Copies of such filing also will be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–030 and should be submitted on or before September 7, 2016.

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[8] FINRA Rules 12100 and 13100 provide that "dispute" means a dispute, claim or controversy, and that it may consist of one or more claims.

[9] 15 U.S.C. 78o–3(b)(6).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[10]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19583 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

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[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78545; File No. SR–NYSEArca–2016–111]

Self-Regulatory Organizations; NYSE Arca, Inc.; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services Related to Tier 1 and Cross Asset Tier 2 Fees and Credits for Orders Executed on the Exchange, and Eliminate the Routable Retail Order Tier

August 11, 2016.

Pursuant to section 19(b)(1)[1] of the Securities Exchange Act of 1934 (''Act'')[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on July 29, 2016, NYSE Arca, Inc. (the ''Exchange'' or ''NYSE Arca'') filed with the Securities and Exchange Commission (''Commission'') the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend the NYSE Arca Equities Schedule of Fees and Charges for Exchange Services (the ''Fee Schedule'') related to Tier 1 and Cross Asset Tier 2 fees and credits for orders executed on the Exchange, and eliminate the Routable Retail Order Tier. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of those statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend the Fee Schedule related to Tier 1 and Cross Asset Tier 2 fees and credits for orders executed on the Exchange.[4] The Exchange also proposes to eliminate the Routable Retail Order Tier. The Exchange proposes to implement the fee change effective August 1, 2016.

Tier 1

Currently, ETP Holders and Market Makers qualify for Tier 1 fees and credits by providing liquidity an average daily share volume per month of 0.70% or more of the United States consolidated average daily volume (''US CADV'').[5] In Tape C Securities, ETP Holders and Market Makers currently receive a credit of $0.0033 per share for orders that provide liquidity to the Book and pay a fee of $0.0029 per share for orders that take liquidity from the Book. The Exchange proposes to amend the fees and credits applicable to ETP Holders and Market Makers for orders executed in Tape C Securities. As proposed, ETP Holders and Market Makers would receive a credit of $0.0032 per share for orders that provide liquidity to the Book in Tape C Securities and would pay a fee of $0.0030 per share for orders that take liquidity from the Book in Tape C Securities. The Exchange is not proposing any other pricing change in Tier 1.

Cross Asset Tier 2

Additionally, Cross Asset Tier 2 fees and credits currently apply to ETP Holders and Market Makers that either (1) provide liquidity an average daily volume share per month of 0.30% or more of the US CADV and are affiliated with an OTP Holder or OTP Firm that provides an ADV of electronic posted executions for the account of a market maker in Penny Pilot issues on NYSE Arca Options (excluding mini options) of at least 0.75% of total Customer equity and ETF option ADV as reported by The Options Clearing Corporation (''OCC''), or (2) provide liquidity an average daily volume share per month of 0.40% or more of the US CADV and are affiliated with an OTP Holder or OTP Firm that provides an ADV of electronic posted executions for the account of a market maker in Penny Pilot issues on NYSE Arca Options (excluding mini options) of at least 0.65% of total Customer equity and ETF option ADV as reported by OCC. Such ETP Holders and Market Makers receive a credit of $0.0033 per share for orders that provide liquidity to the Book in Tape C Securities and pay a fee of $0.0029 per share for orders that take liquidity from the Book in Tape C Securities. The Exchange proposes to amend the fees and credits applicable to ETP Holders and Market Makers for orders executed in Tape C Securities. As proposed, ETP Holders and Market Makers would receive a credit of $0.0032 per share for orders that provide liquidity to the Book in Tape C Securities and pay a fee of $0.0030 per share for orders that take liquidity from the Book in Tape C Securities.

Elimination of Obsolete Pricing

The Fee Schedule currently includes a pricing tier, Routable Retail Order Tier, that has not encouraged ETP Holders and Market Makers to increase their activity to qualify for this pricing tier as significantly as the Exchange had anticipated it would. As a result, the Exchange proposes to remove this pricing tier from the Fee Schedule.

The proposed changes are not otherwise intended to address any other problem, and the Exchange is not aware of any significant problem that the affected market participants would have in complying with the proposed changes.

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[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

[4] The Tier 2 [sic] fees and credits are available for round lots and odd lots with a per share price $1.00 or above.

[5] US CADV would mean the United States Consolidated Average Daily Volume for transactions reported to the Consolidated Tape, excluding odd lots through January 31, 2014 (except for purposes of Lead Market Maker pricing), and excludes volume on days when the market closes early and on the date of the annual reconstitution of the Russell Investments Indexes. Transactions that are not reported to the Consolidated Tape are not included in US CADV. *See* Fee Schedule, footnote 3.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with section 6(b) of the Act,[6] in general, and furthers the objectives of sections 6(b)(4) and 6(b)(5) of the Act,[7] in particular, because it provides for the equitable allocation of reasonable dues, fees, and other charges among its members, issuers and other persons using its facilities and does not unfairly discriminate between customers, issuers, brokers or dealers.

Tier 1

The Exchange believes that the proposed change to increase the fee from $0.0029 per share to $0.0030 per share and to lower the credit from $0.0033 per share to $0.0032 per share for Tier 1 customers in Tape C Securities is reasonable as it is comparable to fees charged and credits paid by at least one other exchange, specifically, Bats BZX Exchange, which charges a fee of $0.0030 per share for orders that remove liquidity in Tape C Securities on that market,[8] and provides a credit that ranges between $0.0020 per share and $0.0032 per share, depending on the amount of volume transacted.[9] The Exchange believes that the proposed fee change is equitable and not unfairly discriminatory because the proposed fees and credits would apply uniformly to all similarly situated ETP Holders and Market Makers and would apply to all Tier 1 orders that add or take liquidity from the Book in Tape C Securities. The Exchange believes that recalibrating the fees and credits will continue to attract order flow to the Exchange, thereby contributing to price discovery on the Exchange and benefiting investors generally.

Cross Asset Tier 2

The Exchange believes that the proposed change to increase the fee from $0.0029 per share to $0.0030 per share and to lower the credit from $0.0033 per share to $0.0032 per share for Cross Asset Tier 2 customers in Tape C Securities is reasonable as it is comparable to fees charged and credits paid by at least one other exchange, specifically, Bats BZX Exchange, which charges a fee of $0.0030 per share for orders that remove liquidity from that exchange in Tape C Securities,[10] and provides a lower cross-asset tier rebate of $0.0029 [sic] per share in Tape C Securities.[11] The Exchange believes that the proposed fee change is equitable and not unfairly discriminatory because the proposed fees and credits would apply uniformly to all similarly situated ETP Holders and Market Makers and would apply to all Cross Asset Tier 2 orders that add or take liquidity from the Book in Tape C Securities. The Exchange believes that recalibrating the fees and credits will continue to attract order flow to the Exchange, thereby contributing to price discovery on the Exchange and benefiting investors generally.

Elimination of Obsolete Pricing

The Exchange believes that it is reasonable to eliminate the obsolete pricing tier from the Fee Schedule because ETP Holders and Market Makers have not increased their activity to qualify for the Routable Retail Order Tier as significantly as the Exchange anticipated they would. The Exchange believes that it is equitable and not unfairly discriminatory to eliminate the Routable Retail Order Tier because, as proposed, the pricing tier would be eliminated entirely—ETP Holders and Market Makers would no longer be able to qualify for this pricing tier. This aspect of the proposed change would therefore result in a more streamlined Fee Schedule.

The Exchange believes that it is subject to significant competitive forces, as described below in the Exchange's statement regarding the burden on competition.

For the foregoing reasons, the Exchange believes that the proposal is consistent with the Act.

B. Self-Regulatory Organization's Statement on Burden on Competition

In accordance with section 6(b)(8) of the Act,[12] the Exchange believes that the proposed rule change would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The proposal to amend the level of fees and credits applicable to Tier 1 customers in Tape C Securities and to Cross Asset Tier 2 customers in Tape C Securities would not place a burden on competition as the proposed changes are comparable to fees and credits for Tape C Securities provided by at least one other exchange.[13] The Exchange believes that the proposed fee changes could promote competition between the Exchange and other execution venues, including those that currently offer comparable transaction pricing, by encouraging additional orders to be sent to the Exchange for execution.

Finally, the Exchange notes that it operates in a highly competitive market in which market participants can readily favor competing venues if they deem fee levels at a particular venue to be excessive or rebate opportunities available at other venues to be more favorable. In such an environment, the Exchange must continually adjust its fees and rebates to remain competitive with other exchanges and with alternative trading systems that have been exempted from compliance with the statutory standards applicable to exchanges. Because competitors are free to modify their own fees and credits in response, and because market participants may readily adjust their order routing practices, the Exchange believes that the degree to which fee changes in this market may impose any burden on competition is extremely limited. As a result of all of these considerations, the Exchange does not believe that the proposed changes will impair the ability of ETP Holders or competing order execution venues to maintain their competitive standing in the financial markets.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change is effective upon filing pursuant to section 19(b)(3)(A)[14] of the Act and subparagraph (f)(2) of Rule 19b–4[15] thereunder, because it establishes a due, fee, or other charge imposed by the Exchange.

At any time within 60 days of the filing of such proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under section 19(b)(2)(B)[16] of the Act to determine whether the proposed rule change should be approved or disapproved.

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[6] 15 U.S.C. 78f(b).

[7] 15 U.S.C. 78f(b)(4) and (5).

[8] *See* Fee Codes and Associated Fees, Bats BZX Exchange Fee Schedule, at *https://batstrading.com/support/fee_schedule/bzx/*.

[9] *See* Add Volume Tiers, Bats BZX Exchange Fee Schedule, at *https://batstrading.com/support/fee_schedule/bzx/*.

[10] *See* Fee Codes and Associated Fees, Bats BZX Exchange Fee Schedule, at *https://batstrading.com/support/fee_schedule/bzx/*.

[11] *See* Add Volume Tiers, Bats BZX Exchange Fee Schedule, at *https://batstrading.com/support/fee_schedule/bzx/*.

[12] 15 U.S.C. 78f(b)(8).

[13] *See supra*, notes 8–11.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(2).

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–NYSEArca–2016–111 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEArca–2016–111. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEArca–2016–111 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19576 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

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[16] 15 U.S.C. 78s(b)(2)(B).

[17] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78544; File No. SR–NYSEMKT–2016–73]

Self-Regulatory Organizations; NYSE MKT LLC; Notice of Filing of Proposed Rule Change Amending Rule 980NY(d) To Provide for the Rejection of Certain Electronic Complex Orders

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 3, 2016, NYSE MKT LLC (the "Exchange" or "NYSE MKT") filed with the Securities and Exchange Commission ("SEC" or "Commission") the proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange proposes to amend Rule 980NY(d) to provide for the rejection of certain Electronic Complex Orders. The proposed rule change is available on the Exchange's Web site at *www.nyse.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of, and basis for, the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange is proposing to amend Rule 980NY(d) to provide for the rejection of certain Electronic Complex Orders ("ECOs").[3] Specifically, the Exchange proposes to reject certain ECOs that may undermine the effectiveness of risk limitation mechanisms designed to protect Market Makers.

The Exchange requires a Market Maker to utilize its risk limitation mechanisms, which automatically remove a Market Maker's quotes in all series of an options class when certain parameter settings are triggered.[4] This functionality is designed to mitigate the risk of multiple executions on a Market Maker's quotes occurring simultaneously across multiple series and multiple option classes. Pursuant to Rule 928NY, the Exchange establishes a time period during which the System calculates: (1) The number of trades executed by the Market Maker in a specified options class; (2) the volume of contracts traded by the Market Maker in a specified options class; or (3) the percentage of the Market Maker's quoted size in the specified class that has been executed (the "risk settings").[5] When a Market Maker has breached its risk settings (*i.e.*, has traded more than the contract or volume limit or cumulative percentage limit of a class during the specified measurement interval), the System will cancel all of the Market Maker's quotes in that class until the Market Maker notifies the Exchange it will resume submitting quotes.[6] The purpose of the risk settings, therefore, is to allow Market Makers to provide liquidity across potentially thousands of options series without being at risk of executing the full cumulative size of all such quotes before being given adequate opportunity to adjust their quotes.

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] Rule 900.3NY(e) defines a Complex Order as any order involving the simultaneous purchase and/or sale of two or more different option series in the same underlying security, for the same account, in a ratio that is equal to or greater than one-to-three (.333) and less than or equal to three-to-one (3.00) and for the purpose of executing [sic] particular investment strategy. Per Rule 980NY, an ECO is a Complex Order that has been entered into the NYSE Amex Options System ("System") for execution. *See* Rule 980NY(preamble).

[4] *See* Rule 928NY(b)(3), (c)(3) and (d)(3). Market Makers are required to utilize one of the three risk settings for their quotes. *See* Commentary .04 to Rule 928NY. Market Makers and ATP Holders may utilize the risk limitation mechanisms for certain orders, but they are not required to do so. *See, e.g.*, Rule 928NY(b)(1), (2); (c)(1), (c)(2).

[5] *See* Rule 928NY(b)(3), (c)(3) and (d)(3). Market Makers are required to utilize one of the three risk settings for its quotes. *See* Commentary .04 to Rule 928NY.

An incoming ECO may execute against quotes or individual orders comprising the Complex Order (the "leg markets") or against ECOs resting in the Consolidated Book.[7] An ECO trading against the leg markets is commonly referred to as "legging out." Current Rule 980NY(c)(ii) provides that an incoming ECO will execute first with the leg markets, ahead of resting ECOs at the same price (*i.e.*, the same total net debit or credit), provided the leg markets can execute the ECO in full or in a permissible ratio.

The execution of certain ECOs against the leg markets can be problematic because ECOs that leg out may execute before triggering a Market Maker's risk settings. Specifically, because the execution of each leg of an ECO is contingent on the execution of the other legs, the execution of all individual leg markets is processed as a single transaction, not as a series of individual transactions. Thus, while the risk settings allow a Market Maker to manage the risks associated with providing liquidity across multiple series of an options class, the settings do not adequately provide this risk protection because the legs of an ECO execute in a single transaction package before processing any subsequent messages. The practical result is that because all legs of an ECO execute before a Market Marker has an opportunity to react, such ECO executions are essentially able to bypass the Market Maker's risk settings.

Of particular concern to the Exchange are ECOs where two or more legs are buying (selling) calls (puts), which are commonly referred to as "directional complex orders." Such directional complex orders are typically geared towards an aggressive directional capture of volatility. Specifically, through a combination of buying or selling of multiple option legs at once, a market participant using one of these strategies is aggressively buying or selling volatility. By contrast, other types of complex strategies are designed to gain exposure to a particular option class' movement.[8] The Exchange has seen a recent increase in the use of directional complex orders as a way to trade against multiple series on the same side of the market without triggering Market Maker risk settings. If the same legs were sent as individual orders, rather than as components of a directional complex order, Market Maker risk settings may have been triggered.[9] The Exchange is concerned that the use of directional complex orders is undermining the important purpose of the Market Makers risk settings, which the Exchange requires Market Makers to use for all quotes.

To address the potential for directional ECOs to undermine the purposes of the Market Maker risk settings, the Exchange proposes to amend Rule 980NY(d). Specifically, the Exchange proposes to reject an ECO if:

(i) Composed of two legs that are (a) both buy orders or both sell orders, and (b) both legs are calls or both legs are puts; *or*

(ii) composed of three or more legs and (a) all legs are buy orders; or (b) all legs are sell orders.[10]

The proposed rule change would not impact the processing of ECOs trading against other ECOs or the priority and allocation of ECOs. The following examples illustrate the types of ECOs that would be rejected under proposed Rule 980NY(d)(4):

Example #1: Illustrating Proposed Rule 980NY(d)(4)(i)

- Buy Call 1, Buy Call 2
- Sell Call 1, Sell Call 2
- Buy Put 1, Buy Put 2
- Sell Put 1, Sell Put 2

Example #2: Illustrating Proposed Rule 980NY(d)(4)(ii)

- Buy Call 1, Buy Call 2, Buy Put 1
- Buy Put 1, Buy Put 2, Buy Put 3
- Buy Call 1, Buy Call 2, Buy Call 3
- Buy Put 1, Buy Put 2, Buy Call 3
- Sell Put 1, Sell Put 2, Sell Call 1

As proposed, the specified directional complex orders would be automatically rejected. Market participants would continue to be able to enter each leg of such complex orders as separate orders. The Exchange believes that the potential risk of these types of directional complex orders undermining the effectiveness of Market Maker risk settings outweighs any potential benefit to ATP Holders submitting such orders.

Finally, the Exchange notes that both the Chicago Board Options Exchange, Inc. ("CBOE") and International Securities Exchange, LLC ("ISE") have recently received Commission approval to revise their rules governing complex orders to implement functionality designed to prevent complex orders from effectively bypassing market maker risk parameters.[11]

Implementation

The Exchange will announce the implementation date of the proposed rule change by Trader Update.

2. Statutory Basis

The Exchange believes that its proposal is consistent with section 6(b) of the Securities Exchange Act of 1934 (the "Act"),[12] in general, and furthers the objectives of section 6(b)(5) of the Act,[13] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to remove impediments to and perfect the mechanism of a free and open market and a national market system, and, in general, to protect investors and the public interest.

The proposed rule change would prevent fraudulent and manipulative acts and practices and would remove impediments to and perfect the mechanism of a free and open market because, it would enable the Exchange to reject (and therefore prevent the execution of) certain directional complex order strategies that may undermine important Market Maker risk settings, which are required for all Market Maker quotes. The Exchange believes that rejecting the specified directional orders outright provides clarity as to the disposition of ECOs submitted by market participants and assures that the Market Maker risk settings will operate as intended. The Exchange notes that other markets have amended their rules to prevent directional complex orders from undermining market maker risk settings and do not allow such orders to leg out.[14] Because of the non-traditional nature of these directional complex orders, the Exchange believes it unlikely that they would execute against complex interest. Accordingly, the Exchange believes rejecting the orders outright (as opposed to simply preventing them from legging out) would have the same practical impact for the order-sending firms and would be the most effective and transparent means of handling these orders. Furthermore, the Exchange believes that the risk of the specified directional complex orders undermining the efficacy of Market Maker risk settings outweighs any potential benefit to ATP Holders submitting such orders packaged as ECOs. The Exchange notes that market participants would continue to be able to enter each leg of such complex orders as separate orders. The Exchange also believes this proposal would protect investors and the public interest because it would help eliminate a degree of unnecessary risk borne by Market Makers when fulfilling their quoting obligations to the markets and would encourage them to contribute liquidity on the Exchange. The Exchange believes the strengthened risk settings would encourage Market Makers to provide tighter and deeper markets, to the benefit of all market participants.

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[6] *See* Commentary .01 to Rule 928NY (requiring that a Market Maker request that it be re-enabled after a breach of its risk settings).

[7] *See* Rule 980NY(c)(ii).

[8] The Exchange notes that the majority of ECOs are calendar and vertical spreads, butterflies and straddles, which are designed to hedge the potential move of the underlying security or to capture premium from an anticipated market event.

[9] For example, if individual orders to buy 10 contracts for the Jan 30 call, Jan 35 call and Jan 40 call are entered, each is processed as it is received and the Market Maker risk settings are calculated following the execution of each 10-contract order. Thus, if either the first order or the second order trigger a Market Maker's risk settings, the System would cancel all of the Market Maker's quotes in that class until the Market Maker notifies the Exchange it will resume submitting quotes (*see* Commentary .01 to Rule 928NY). However, if an ECO to buy all three of these options with a quantity of 10 contracts is entered and is executed against the leg markets, the Market Maker risk settings for quotes in the leg market are calculated only after the execution of all 30 contracts (the sum of the three legs of 10 contracts each) because the execution of all individual leg markets is processed as a single transaction, not as a series of individual transactions.

[10] *See* proposed Rule 980NY(d). The Exchange also proposes to delete the words "Types of" in the first paragraph because sub-paragraphs (1)–(4) of paragraph (d) do not describe the "types of" ECOs, but rather describe the requirements for such orders.

[11] *See* Securities Exchange Act Release Nos. 73023 (September 9, 2014) 79 FR 55033 (September 15, 2014) (SR–ISE–2014–10) and 72986 (September 4, 2014) 79 FR 53798 (September 10, 2014) (SR–CBOE–2014–017) (Approval Order). *See also* Securities Exchange Act Release Nos. 76106 (October 8, 2015) 80 FR 62125 (October 15, 2015) (SR–CBOE–2014–081); 77297 (March 4, 2016), 81 FR 12764 (March 10, 2016) (SR–CBOE–2016–014) (further amending the complex order rule, as modified by the Approval Order, to limit a potential source of unintended market maker risk). The Exchange acknowledges that, unlike this proposal, CBOE and ISE do not reject the offending ECOs outright.

[12] 15 U.S.C. 78f(b).

[13] 15 U.S.C. 78f(b)(5).

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change would impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. The Exchange does not believe that the proposed change would impose any burden on competition that is not necessary in furtherance of the purposes of the Act because it is designed to prevent certain ECOs from executing before triggering Market Maker risk settings, thereby undermining this functionality. The Exchange believes the proposed change would strengthen Market Makers risk settings, which would, in turn, help eliminate a degree of risk borne by Market Makers when fulfilling their quoting obligations to the markets. The Exchange believes the strengthened risk settings would encourage Market Makers to provide tighter and deeper markets, to the benefit of all market participants. Because market participants would continue to be able to enter each leg of such complex orders as separate orders (as opposed to packaging as an ECO), the proposed change would also not pose an undue burden on market participants that want to enter such orders. The Exchange does not believe that the proposed change would impose a burden on competing options exchanges, as at least two options exchanges have substantively similar rules in place.[15]

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received with respect to the proposed rule change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange believes that the proposal qualifies for accelerated effectiveness in accordance with section 19(b)(2) of the Act. The Exchange believes that there is good cause for the Commission to accelerate effectiveness because the proposed rule change is consistent with the rules of at least two competing options markets, which have amended their rules to prevent directional complex orders from undermining market maker risk settings and do not allow such orders to leg out.[16] The Exchange would like to similarly enhance the protection it provides to Market Makers. Because of the non-traditional nature of these directional complex orders, the Exchange believes it unlikely that they would execute against complex interest. Accordingly, the Exchange believes rejecting the orders outright (as opposed to simply preventing them from legging out) would have the same practical impact for the order-sending firms and would be the most effective and transparent means of handling these orders. Thus, accelerated approval of this proposal would enable the Exchange to implement the rule change without delay, thereby strengthening market maker risk settings and enhancing the competitiveness of the Exchange.

In addition, the Exchange believes that the proposed rejection of the specified directional complex orders would prevent such orders from executing before triggering (and thus, bypassing) the Market Maker risk settings. The Exchange believes that the potential risk of these types of directional complex orders undermining the effectiveness of Market Maker risk settings outweighs any potential benefit to ATP Holders submitting such orders. Market participants would continue to be able to enter each leg of such complex orders as separate orders. Thus, the Exchange believes good cause exists to accelerate effectiveness of this proposal because it would help eliminate a degree of unnecessary risk borne by Market Makers when fulfilling their quoting obligations to the markets, which would in turn benefit all market participants because Market Makers would be encouraged to provide tighter and deeper markets.

Within 45 days of the date of publication of this notice in the **Federal Register** or within such longer period up to 90 days (i) as the Commission may designate if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve or disapprove the proposed rule change, or

(B) institute proceedings to determine whether the proposed rule change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–NYSEMKT–2016–73 on the subject line.

Paper Comments

- Send paper comments in triplicate to Brent J. Fields, Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–NYSEMKT–2016–73. This file number should be included on the subject line if email is used. To help the

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[14] *See supra* n. 11.

[15] *See supra* n. 11.

[16] *See supra* n. 11.

Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–NYSEMKT–2016–73 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[17]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19575 Filed 8–16–16; 8:45 am]

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SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78542; File No. SR–BatsBYX–2016–20]

Self-Regulatory Organizations; Bats BYX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Logical Port Fees

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2016, Bats BYX Exchange, Inc. (the "Exchange" or "BYX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-Members of the Exchange pursuant to BYX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule to modify the billing policy for the logical port fees. The Exchange currently charges for logical ports (including Multicast PITCH Spin Server and GRP ports) $500 per port per month. A logical port represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-Member and grants that Member or non-Member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. The Exchange's Multicast PITCH data feed is available from two primary feeds, identified as the "A feed" and the "C feed", which contain the same information but differ only in the way such feeds are received. The Exchange also offers two redundant feeds, identified as the "B feed" and the "D feed". Logical port fees are limited to logical ports in the Exchange's primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees to all Member's and non-Member's logical ports.

The Exchange proposes to clarify within its fee schedule how monthly fees for logical ports may be pro-rated. As proposed, new requests will be pro-rated for the first month of service. Cancellation requests are billed in full month increments as firms are required to pay for the service for the remainder of the month, unless the session is terminated within the first month of service.

Implementation Date

The Exchange proposes to implement these amendments to its fee schedule on August 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with section 6(b)(4) of the Act,[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The proposed rule change seeks to provide clarity to subscribers regarding the Exchange's pro-rata billing policy for logical ports by describing how logical port fees may be pro-rated for a new request and upon cancellation. The Exchange believes that the proposed pro-rata billing of fees for logical ports is reasonable in that it is similar to how port fees are pro-rated by the Nasdaq Stock Market LLC ("Nasdaq").[8]

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[17] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term "Member" is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." *See* Exchange Rule 1.5(n).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

The Exchange operates in a highly competitive market in which exchanges offer connectivity services as a means to facilitate the trading activities of Members and other participants. Accordingly, fees charged for connectivity are constrained by the active competition for the order flow of such participants as well as demand for market data from the Exchange. If a particular exchange charges excessive fees for connectivity, affected Members will opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, an exchange charging excessive fees would stand to lose not only connectivity revenues, but also revenues associated with the execution of orders routed to it by affected members, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendment to its fee schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act in that it is simply designed to set forth the Exchange's pro-rata billing for logical ports and is similar to that currently offered by one of the Exchange's competitors.[9] Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including logical port fees, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The Exchange also does not believe the proposed rule change would impact intramarket competition as it would apply to all Members and non-Members equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to section 19(b)(3)(A) of the Act[10] and paragraph (f) of Rule 19b–4 thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–BatsBYX–2016–20 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBYX–2016–20. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBYX–2016–20, and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19573 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78555; File No. SR–IEX–2016–12]

Self-Regulatory Organizations: Investors Exchange LLC; Notice of Filing and Immediate Effectiveness of Proposed Rule Change To Conform to Rules of the Financial Industry Regulatory Authority

August 11, 2016.

Pursuant to Section 19(b)(1)[1] of the Securities Exchange Act of 1934 (the "Act")[2] and Rule 19b–4 thereunder,[3] notice is hereby given that, on August 9, 2016, the Investors Exchange LLC ("IEX" or the "Exchange") filed with the Securities and Exchange Commission (the "Commission") the proposed rule change as described in Items I and II below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

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[8] *See* Nasdaq Price List—Trade Connectivity *available at http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2#connectivity.* The Exchange notes that, unlike as proposed by the Exchange, Nasdaq does not pro-rate where the session is terminated within the first month of service.

[9] *Id.*

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 15 U.S.C. 78a.

[3] 17 CFR 240.19b–4.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

Pursuant to the provisions of Section 19(b)(1) under the Securities Exchange Act of 1934 ("Act"),[4] and Rule 19b–4 thereunder,[5] Investors Exchange LLC ("IEX" or "Exchange") is filing with the Securities and Exchange Commission ("Commission") a proposed rule change to conform Rule 3.260(d) and 5.110(e) to corresponding rules of the Financial Industry Regulatory Authority ("FINRA"). The Exchange has designated this proposal as "non-controversial" and provided the Commission with the notice required by Rule 19b–4(f)(6)(iii) under the Act.[6]

The text of the proposed rule change is available at the Exchange's Web site at *www.iextrading.com,* at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statement may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in Sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

Pursuant to Rule 17d–2 under the Act,[7] and subject to Commission approval, the Exchange and FINRA has entered into an agreement to allocate regulatory responsibility for common rules (the "17d–2 Agreement").[8] The 17d–2 Agreement covers common members of the Exchange and FINRA and allocates to FINRA regulatory responsibility, with respect to common members, for the following: (1) Examination of common members of the Exchange and FINRA for compliance with certain federal securities laws, rules and regulations and rules of the Exchange that the Exchange certifies are identical or substantially similar to FINRA rules; (2) investigation of common members of the Exchange and FINRA for violations of certain federal securities laws, rules and regulations, or Exchange rules that the Exchange certifies as identical or substantially identical to a FINRA rule; and (3) enforcement of compliance by common members with certain federal securities laws, rules and regulations, and the rules of the Exchange that the Exchange certifies as identical or substantially similar to FINRA rules.

The 17d–2 Agreement will include a certification by the Exchange that states that the requirements contained in certain Exchange rules are identical to, or substantially similar to, certain FINRA rules that have been identified as comparable. To conform to comparable FINRA rules for the purposes of the 17d–2 Agreement, as well as to make changes that IEX believes are appropriate, the Exchange proposes to amend Exchange Rules 3.260(d) and 5.110(e) to harmonize with FINRA Rules as described below.

IEX Rule 3.260

IEX Rule 3.260 governs discretionary accounts and contains certain prohibitions and requirements as follows:

> (a) *Excessive Transactions*—The rule prohibits a Member from effecting purchase or sale transactions in a customer's account, with respect to which such member (or its agent or employee) has discretion, which are excessive in size or frequency in view of the financial resources and character of such account.
>
> (b) *Authorization and Acceptance of Account*—The rule provides that no Member or Registered Representative shall exercise any discretionary power in a customer's account unless such customer has given prior written authorization to a stated individual or individuals and the account has been accepted by the Member, as evidenced in writing by the Member or the partner, officer or manager, duly designated by the Member, in accordance with IEX Rule 5.110.
>
> (c) *Approval and Review of Transactions*—The rule provides that the Member or the person duly designated shall approve promptly in writing each discretionary order entered and shall review all discretionary accounts at frequent intervals in order to detect and prevent transactions which are excessive in size or frequency in view of the financial resources and character of the account.
>
> (d) *Exceptions*—The rule provides an exception for discretion as to the price at which or the time when an order given by a customer for the purchase or sale of a definite amount of a specified security shall be executed, except that the authority to exercise time and price discretion will be considered to be in effect only until the end of the business day on which the customer granted such discretion, absent a specific, written contrary indication signed and dated by the customer. This limitation shall not apply to time and price discretion exercised in an institutional account, as defined in IEX Rule 5.110 pursuant to valid Good-Till-Canceled instructions issued on a "not-held" basis. Any exercise of time and price discretion must be reflected on the order ticket.

IEX Rule 3.260 is identical to NASD Rule 2510 (which is a FINRA rule) except that paragraph (d) of the IEX rule does not contain an exception contained in NASD Rule 2510(d) for bulk exchanges at net asset value of money market mutual funds utilizing negative response letters provided the bulk exchange is limited to situations involving mergers and acquisitions of funds, changes of clearing members and exchange of funds used in sweep accounts, the negative response letter contains a tabular comparison of the nature and amount of the fees charged by each fund, the negative response letter contains a comparative description of the investment objectives of each fund and a prospectus of the fund to be purchased, and the negative response feature will not be activated until at least 30 days after the date on which the letter was mailed.

To harmonize IEX Rule 3.260 with NASD Rule 2510, the Exchange proposes to adopt an identical exception for bulk transfers as is contained in NASD Rule 2510(d) so that it may be incorporated into the 17d–2 Agreement in its entirety. The exception was added to NASD rules in 1992 in order to eliminate an obstacle to the efficient and timely execution of bulk exchanges of money market mutual funds in the situations set forth in NASD Rule 2510. In Notice to Members 93–1 announcing the rule change,[9] the NASD explained the reason for adoption of the exception as follows:

> The NASD recognized that it is often necessary to notify hundreds and, sometimes, several thousand money market mutual fund share-owners of an impending fund exchange. It may be an extremely difficult, if not impossible, administrative task to contact each non-replier and solicit approval of the fund exchange. At best, contacting individuals for approval results in considerable delays and added cost. The NASD determined that, by eliminating an obstacle to the efficient and timely execution of such bulk exchanges, where customers are at little or no risk, customers and NASD members would benefit.

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[4] 15 U.S.C. 78s(b)(1).

[5] 17 CRF 240.19b–4.

[6] 17 CFR 240.19b–4(f)(6)(iii).

[7] 17 CFR 240.17d–2.

[8] *See* Securities Exchange Act Release No. 78434 (July 28, 2016) (File No. 4–700).

[9] *See http://finra.complinet.com/en/display/display.html?rbid=2403&element_id=1638.*

Although such bulk transfers cannot be effected on the Exchange, IEX believes it is appropriate to include the exception provided in NASD Rule 2510(d) to eliminate the obstacles and provide the benefits identified by the NASD in adopting the exception, as well as to enable incorporation of IEX Rule 3.260 into the 17d–2 Agreement in its entirety. Incorporating the exception into IEX Rule 3.260 would provide appropriate flexibility to allow IEX Members to perform bulk exchanges in the limited situations specified in the rule in an efficient manner that is designed to protect investors and the public interest. Absent the exception, IEX Members would technically be prohibited from effecting bulk transfers in the manner permitted by FINRA rules.[10]

IEX Rule 5.110(e)

IEX Rule 5.110(e) governs the responsibility of an IEX Member to investigate applicants for registration, including that ". . . each member shall establish and implement written procedures reasonably designed to verify the accuracy and completeness of the information contained in an applicant's Form U4 [11] no later than 30 calendar days after the form is filed with IEX." The rule is substantially identical to FINRA Rule 3110(e) except that in the sentence quoted above, FINRA Rule 3110(e) specifies that the verification requirement applies only to an applicant's initial or transfer Form U4.[12] The Exchange inadvertently omitted the "initial or transfer" language in Rule 5.110(e). The Exchange proposes to harmonize IEX Rule 5.110(e) with FINRA Rule 3110(e) by adding the omitted language contained in the FINRA rule in order to clarify the requirement, avoid confusion to IEX Members in applying the relevant provision, and enable Rule 5.110 to be incorporated into the 17d–2 Agreement in its entirety. Adding the omitted language will make clear to IEX Members that the verification requirement does not apply to updates or amendments to a registered person's Form U4 [13] if such filing is not an initial or transfer Form U4. IEX believes that in determining to require verification for initial and transfer Forms U4, FINRA imposes an appropriate requirement consistent with public interest and investor protection concerns in that FINRA requires verification at key times in a registered person's employment. In this regard, IEX notes that FINRA has substantial expertise administering the CRD system and overseeing its members (and those of its client national securities exchanges) Form U4 reporting obligations. Accordingly, IEX believes that it is appropriate to harmonize with FINRA's approach on what triggers should be required for Members to verify the accuracy and completeness of Form U4 information for their registered personnel, and that the triggers are consistent with investor protection and the public interest. Moreover, for IEX Members that are also FINRA members, the proposed change will align IEX rules with FINRA rules thereby alleviating potential confusion.

2. Statutory Basis

IEX believes that the proposed rule change is consistent with the provisions of Section 6 of the Act,[14] in general and furthers the objectives of Sections 6(b)(5) of the Act,[15] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, and to remove impediments to and perfect the mechanism of a free and open market and a national market system and, in general, to protect investors and the public interest.

With respect to the proposed change to add an exception to Rule 3.260 to permit bulk transfers under the specified circumstances, the Exchange believes that the exception is consistent with Section 6(b)(5) of the Act [16] because the exception is narrowly drawn and includes protections designed to help prevent fraudulent and manipulative acts and protect investors and the public interest. The exception is limited to situations involving mergers and acquisitions of funds, changes of clearing members and exchange of funds used in sweep accounts. The Exchange does not believe that these situations raise concerns regarding abuse of discretion in customer accounts by the Member, but rather are more administrative in nature. In addition, and as described above, the exception to permit negative response letters in lieu of prior written authorization from customers for bulk exchanges includes four requirements that are designed to protect customers—the negative response letter must contain a tabular comparison of the nature and amount of the fees charged by each fund, the negative response letter must contain a comparative description of the investment objectives of each fund, a prospectus of the fund to be purchased must be included with the negative response letter, and the negative response feature may not be activated until at least 30 days after the date on which the letter was mailed. These protections provide relevant disclosures to customers regarding the bulk exchange and 30 days to potentially contact the Member to object to the exchange. Based on these considerations, IEX believes it is appropriate to include the exception provided in NASD Rule 2510(d) to eliminate the obstacles and provide the benefits identified by the NASD in adopting the exception. Incorporating the exception into IEX Rule 3.260 would provide appropriate flexibility to allow IEX Members to perform bulk exchanges in the limited situations specified in the rule in an efficient manner that is designed to protect investors and the public interest, as well as to remove impediments to and perfect the mechanism of a free and open market and a national market system.

Further, as noted above, each IEX Member subject to Rule 3.260 must also be a FINRA member. In this regard, the Exchange believes that the proposed rule change will further the objectives of Section 6(b)(5) of the Act [17] by providing greater harmonization between IEX and FINRA rules of similar purpose, enable IEX to incorporate IEX Rule 3.260 in its entirety into the pending 17d–2

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[10] Each IEX Member subject to IEX Rule 3.260 is required to be a FINRA member, pursuant to Section 15(b)(8) of the Act, since the rule relates to customer accounts and the Member would thus be ineligible for the exemption provided in Rule 15b9–1 under the Act.

[11] Form U4 is the Uniform Application for Securities Industry Registration or Transfer which must be used by representatives of broker-dealers, among other entities, to become registered in the appropriate jurisdictions and/or SROs. Both FINRA and IEX, as well as all other national securities exchanges, require representatives of broker-dealer members to register on Form U4.

[12] In its proposed rule filing to adopt FINRA Rule 3110 in its current form, FINRA stated that the term "initial Form U4" refers to the Form U4 filing required when an individual is registering with a FINRA member for the first time, including in the context of dual registration, or is registering with a FINRA member after more than two years have passed since the individual was last registered with a FINRA member. The term "transfer Form U4" refers to the Form U4 filing required when a registered person transfers from one FINRA member to another FINRA member. (*See,* SR–FINRA–2014–038). Since FINRA administers the Form U4 filing process in its CRD system, in part on behalf of IEX, the Exchange would apply the same meanings in the application of Rule 5.110(e).

[13] The instructions to the Form U4, state that the "individual is under a continuing obligation to amend and update information required by Form U4 as changes occur." See, Form U4 Uniform Application for Securities Industry Registration or Transfer, available at *http://www.finra.org/sites/default/files/AppSupportDoc/p015111.pdf.*

[14] 15 U.S.C. 78f.

[15] 15 U.S.C. 78f(b)(5).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78f(b)(5).

Agreement between the Exchange and FINRA (subject to SEC approval), resulting in less burdensome and more efficient regulatory compliance. As such, the proposed rule change would foster cooperation and coordination with persons engaged in facilitating transactions in securities and would remove impediments to and perfect the mechanism of a free and open market and a national market system in accordance with Section 6(b)(5) of the Act.[18]

IEX believes that the proposed change to Rule 5.110(e) is consistent with Section 6(b)(5) of the Act[19] because it will serve to correct an inadvertent omission in the rule thereby clarifying the applicable verification requirement for IEX Members. As discussed above in the Purpose section, IEX believes that the FINRA Form U4 verification requirements are designed to protect investors and the public interest by requiring verification at key times in a registered person's employment. In addition, and as noted above, FINRA has substantial expertise administering the CRD system and overseeing its members (and those of its client national securities exchanges) Form U4 reporting obligations through SEC approved rules.[20] Accordingly, IEX believes that the proposed rule change would further the objectives of Section 6(b)(5) of the Act[21] by imposing appropriately balanced Form U4 verification requirements that are designed to prevent fraudulent and manipulative acts and practices and to promote just and equitable principles of trade. Further, the Exchange believes that providing greater harmonization between IEX and FINRA rules of similar purpose will result in less burdensome and more efficient regulatory compliance for IEX Members that are also FINRA members, and facilitate FINRA's performance of its regulatory performance under the pending 17d–2 Agreement (subject to SEC approval), thereby removing impediments to and perfecting the mechanism of a free and open market and a national market system, consistent with the objectives of Section 6(b)(5). In addition, alignment of IEX rules with FINRA rules will alleviate any confusion among market participants regarding the applicable verification requirements, including for IEX Members that are not FINRA members.

B. Self-Regulatory Organization's Statement on Burden on Competition

IEX does not believe that the proposed rule change will result in any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act, as amended. The proposed rule change is not designed to address any competitive issues but rather to provide greater harmonization among Exchange and FINRA rules of similar purpose, resulting in less burdensome and more efficient regulatory compliance for common members and facilitating FINRA's performance of its regulatory performance on the pending 17d–2 Agreement (subject to SEC approval). Moreover, harmonization of the specified IEX's rules with FINRA rules will promote competition by removing disparate requirements between IEX Members and FINRA members.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The Exchange has designated this rule filing as non-controversial under Section 19(b)(3)(A)[22] of the Act and Rule 19b–4(f)(6)[23] thereunder. Because the foregoing rule does not (i) significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days from the date on which it was filed, or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest, provided that the self-regulatory organization has given the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change or such shorter time as designated by the Commission,[24] the proposed rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[25] and Rule 19b–4(f)(6) thereunder.[26]

A proposed rule change filed under Rule 19b–4(f)(6)[27] normally does not become operative prior to 30 days after the date of the filing. However, pursuant to Rule 19b–4(f)(6)(iii),[28] the Commission may designate a shorter time if such action is consistent with the protection of investors and the public interest. The Exchange has asked the Commission to waive the 30-day operative delay so that the Exchange may harmonize its rules with FINRA to coincide with IEX's launch of exchange operations during a security-by-security phase-in period scheduled to begin on August 19, 2016. The Exchange represents that the proposed changes do not present any new or novel issues as IEX is harmonizing these two rules to the comparable rules of FINRA. The Exchange also represents that further harmonizing them now will allow them to coincide with the recently effective bilateral 17d–2 plan, which should reduce burdens on members while the increased coordination should promote investor protection. Because IEX's proposal does not raise any new or novel issues and seeks only to harmonize two IEX rules to the corresponding rules of FINRA that are covered by the FINRA–IEX bilateral 17d–2 plan, the Commission believes that waiver of the operative delay is consistent with the protection of investors and the public interest because it will allow IEX to update those two rules to coincide with the operation of the bilateral 17d–2 plan, which the Commission recently declared effective, as IEX begins operations as an exchange.[29]

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings under Section 19(b)(2)(B)[30] of the Act to determine whether the proposed rule change should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

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[18] 15 U.S.C. 78f(b)(5).

[19] 15 U.S.C. 78f(b)(5).

[20] *See* Release No. 34–73966, File No. SR–FINRA–2014–038 (December 30, 2014); 80 FR 546 (January 6, 2015).

[21] 15 U.S.C. 78f(b)(5).

[22] 15 U.S.C. 78s(b)(3)(A).

[23] 17 CFR 240.19b–4(f)(6).

[24] The Exchange has fulfilled this requirement.

[25] 15 U.S.C. 78s(b)(3)(A).

[26] 17 CFR 240.19b–4(f)(6).

[27] 17 CFR 240.19b–4(f)(6).

[28] 17 CFR 240.19b–4(f)(6)(iii).

[29] For purposes only of accelerating the operative date of this proposal, the Commission has considered the proposed rule's impact on efficiency, competition, and capital formation. 15 U.S.C. 78c(f).

[30] 15 U.S.C. 78s(b)(2)(B).

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov.* Please include File Number SR–IEX–2016–12 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–IEX–2016–12. This file number should be included in the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549 on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing will also be available for inspection and copying at the IEX's principal office and on its Internet Web site at *www.iextrading.com.* All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–IEX–2016–12 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[31]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19585 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

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[31] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78557; File No. SR–FINRA–2016–015]

Self-Regulatory Organizations; Financial Industry Regulatory Authority, Inc.; Notice of Filing of Amendment No. 1 and Order Granting Accelerated Approval of a Proposed Rule Change Amending Rule 12904 (Awards) of the Code of Arbitration Procedure for Customer Disputes and Rule 13904 (Awards) of the Code of Arbitration Procedure for Industry Disputes To Permit Award Offsets in Arbitration, as Modified by Amendment No. 1

August 11, 2016.

I. Introduction

On May 3, 2016, Financial Industry Regulatory Authority, Inc. ("FINRA") filed with the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Exchange Act")[1] and Rule 19b–4 thereunder,[2] a proposed rule change to provide that absent specification to the contrary in an arbitration award, when arbitrators order opposing parties to pay each other damages, the monetary awards shall offset, and the party that owes the larger amount shall pay the net difference.

The proposed rule change was published for comment in the **Federal Register** on May 23, 2016.[3] The public comment period closed on June 13, 2016. On July 1, 2016, FINRA extended the time period in which the Commission must approve the proposed rule change, disapprove the proposed rule change, or institute proceedings to determine whether to approve or disapprove the proposed rule change to August 19, 2016. The Commission received nine comment letters in response to the Notice.[4] On July 15, 2016, FINRA responded to the comment letters received in response to the Notice and filed an amendment to the proposed rule change ("Amendment No. 1").[5]

This order provides notice of filing of Amendment No. 1 and approves the proposal, as modified by Amendment No. 1, on an accelerated basis.

II. Description of the Proposed Rule Change

Original Proposal

FINRA Rule 12904 (Awards) of the Code of Arbitration Procedure for Customer Disputes ("Customer Code") and Rule 13904 (Awards) of the Code of Arbitration Procedure for Industry Disputes ("Industry Code") (together, "Codes") address awards issued by arbitrators at the FINRA Office of Dispute Resolution forum. Currently, these rules provide, among other matters, that awards must be in writing and signed by a majority of the arbitrators or as required by applicable law. The rules itemize required elements of awards, including a statement of the damages awarded, and provide that all monetary awards shall be paid within 30 days of receipt unless a motion to vacate has been filed in a court of competent jurisdiction.[6] Rules 12904 and 13904 do not, however, require arbitrators to specify whether opposing parties in a case should offset amounts awarded to each other.

Accordingly, FINRA has stated that when arbitrators order opposing parties in a case to pay each other monetary damages, but do not specify whether the party that owes the higher amount must pay the net difference, the lack of clarity has resulted in parties asking arbitrators to revise an award after a case has closed or in post-award litigation.[7] For example, arbitrators may award damages to a firm because an associated person failed to pay money owed on a promissory note and award a lesser amount to the associated person on a counterclaim. If the arbitrators do not specify that awards should be offset, the firm may be required to pay the counterclaim even if the associated person refuses or is unable to pay the larger amount.[8] FINRA states that the offset issue could also arise in customer cases, such as those involving margin account disputes.[9]

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[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Exchange Act Release No. 77844 (May 17, 2016), 81 FR 32359 (May 23, 2016) (File No. SR–FINRA–2016–015) ("Notice").

[4] *See* Letters from Leonard Steiner, Steiner & Libo, dated May 9, 2016 ("Steiner Letter"); Steven B. Caruso, Maddox Hargett Caruso, P.C., dated May 18, 2016 ("Caruso Letter"); George H. Friedman, Adjunct Professor of Law, Fordham Law School, and immediate past FINRA Director of Arbitration, dated May 23, 2016 ("Friedman Letter"); James L. Komie, Schuyler, Roche and Crisham, P.C., dated June 7, 2016 ("Komie Letter"); Thomas E. Wall, Attorney at Law and Public Arbitrator for FINRA, dated June 11, 2016 ("Wall Letter"); Kevin Carroll, Managing Director and Associate General Counsel, Securities Industry and Financial Markets Association, dated June 13, 2016 ("SIFMA Letter"); David T. Bellaire, Executive Vice President and General Counsel, Financial Services Institute, dated June 13, 2016 ("FSI Letter"); Hugh Berkson, President, Public Investors Arbitration Bar Association, dated June 13, 2016 ("PIABA Letter"); Bev Kennedy, Oakville, Ontario, Canada, dated June 26, 2016 ("Kennedy Letter"). Comment letters are available at *www.sec.gov.*

[5] *See* Letter from Margo A. Hassan, Associate Chief Counsel, FINRA, to the Commission, dated July 15, 2016 ("FINRA Letter"). The FINRA Letter and the text of Amendment No. 1 are available on FINRA's Web site at *http://www.finra.org,* at the principal office of FINRA, at the Commission's Web site at *http://www.sec.gov/rules/sro/finra/2015/34-75655.pdf,* and at the Commission's Public Reference Room.

[6] *See* Notice at 32359.

[7] *See id.*

FINRA is proposing to amend Rules 12904(j) and 13904(j) to provide that, absent specification to the contrary in an award, when arbitrators order opposing parties to pay each other damages, the monetary awards shall offset, and the party that owes the larger amount shall pay the net difference.[10]

FINRA is also proposing to replace the bullets in Rules 12904 and 13904 with numbers in order to make it easier to identify and cite subparts of the rule.[11]

Proposal as Modified by Amendment No. 1

In response to comments [12] (discussed below), FINRA is proposing to amend proposed Rules 12904(j) and 13904(j), to provide that, absent specification to the contrary in an award, when arbitrators order opposing parties to make payments to one another, the monetary awards shall offset, and the party assessed the larger amount shall pay the net difference. The proposed amendment would effectively replace the word "damages" with "payments" in order to capture those portions of awards attributable to amounts other than damages (*e.g.,* costs and fees).

III. Comment Summary and FINRA's Response

As noted above, the Commission received nine comment letters on the proposed rule change [13] and a response letter from FINRA.[14] As discussed in more detail below, six of the nine commenters expressed support for the proposal; [15] two of the nine commenters expressed opposition to the proposed rule change; [16] and, one commenter did not address the subject matter of the proposal.[17]

Default Favoring Award Offsets

Six commenters supported a default in favor of award offsets,[18] stating, among other things, that the proposal "is a fair, equitable and reasonable approach," [19] "would . . . provide useful guidance to parties in . . . drafting their pleading," [20] "would promote the finality of arbitration awards by reducing the need for post-award court litigation seeking to modify awards to provide for offset," [21] "is a positive step forward in enhancing and improving the FINRA Dispute Resolution Process," [22] "is fair and appropriate and offers an important clarification," [23] and "makes common sense." [24]

Two commenters opposed providing a default in favor of award offsets on the basis that parties already have the ability to request, and do request, that panels "offset the competing claims in rendering their final awards." [25] In addition, one of these commenters stated that "[i]f the panel decides not to do an offset, it is not for FINRA to mandate one." [26]

In its response, FINRA stated its belief "that the proposed rule change will eliminate ambiguity and reduce the risk of post-award disputes." [27] FINRA further responded that the proposed change "would likely reduce legal expenses to the party owed greater damages by eliminating the need to apply for the reopening of the case or going to court to seek award offsets, or seek other redress." [28] Finally, FINRA noted that the "proposed rule does not override arbitrator discretion" and stated that if the proposal is approved, "FINRA will alert arbitrators to the amendment and will revise the Award Information Sheet to inform arbitrators of the offset default when arbitrators are silent on the issue." [29]

Amendment Requests

Two of the six commenters supporting FINRA's proposal suggested that FINRA also address additional related concerns.[30] One commenter generally in support of the proposal urged FINRA to also address the issue of unpaid arbitration awards for investors by implementing a national recovery pool.[31] In response to this suggestion, FINRA stated that the "issue of unpaid awards is beyond the scope of the proposed rule change." [32] Another commenter "strongly supported" the proposal, but noted that the proposal as drafted would have the effect of limiting the default in favor of offset to only those awards specifically characterized by arbitrators as "damages." [33] The commenter noted that arbitration awards, in addition to damages, may "consist of, and be characterized as, damages, costs, fees, etc." [34] The commenter expressed its belief that the "[p]roposal was never intended to be strictly limited to 'damages' offsets," and therefore requested that FINRA revise the proposal "so that it is not susceptible to such a narrow reading" by: (i) Replacing the phrase "pay each other damages" in the proposal with "make payments to one another," and (ii) replacing the phrase "that owes" with "assessed." [35] In its response, FINRA agreed "that the proposal was not intended to be strictly limited to 'damages' offsets" and proposed to amend the proposed rule change "for purposes of clarity" as set forth in the previous sentence.[36]

IV. Discussion and Commission Findings

After careful review of the proposed rule change, as modified by Amendment No. 1, the comment letters, and FINRA's response to the comments, the Commission finds that the proposal, as modified by Amendment No. 1, is consistent with the requirements of the Exchange Act and the rules and regulations thereunder that are applicable to a national securities association.[37] Specifically, the Commission finds that the rule change is consistent with section 15A(b)(6) of the Exchange Act,[38] which requires, among other things, that FINRA rules be designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest.

As stated in the Notice, FINRA believes that "providing a default in favor of offset when arbitrators fail to address the issue in an award would benefit forum users by eliminating ambiguity and reducing the risk of post-award disputes."[39] More specifically, FINRA believes that the proposed rule change will "mitigate the risk of failure to pay by an opposing party that may arise when multiple parties in a dispute are found to owe non-equivalent awards simultaneously."[40] Consequently, FINRA believes that the proposal would "likely reduce legal expenses to the party owed greater damages by eliminating the need to apply for the reopening of the case or going to court to seek award offsets, or seek other redress."[41]

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[8] *See id. See also, e.g., UBS Financial Services, Inc. (UBS)* v. *Thomas A. Mann (Mann),* No. 2:2014cv10621, 2014 WL 1746249 (E.D. Mich. Apr. 30, 2014).

[9] *See* Notice at 32359.

[10] *See id.*

[11] *See id.*

[12] *See* SIFMA Letter at 2.

[13] *See supra* note 4.

[14] *See supra* note 5.

[15] *See* Caruso Letter, Friedman Letter, Komie Letter, SIFMA Letter, FSI Letter, and PIABA Letter.

[16] *See* Steiner Letter and Wall Letter.

[17] *See* Kennedy Letter.

[18] *See supra* note 15.

[19] Caruso Letter.

[20] Friedman Letter.

[21] Komie Letter.

[22] FSI Letter.

[23] SIFMA Letter.

[24] PIABA Letter.

[25] *See* Steiner Letter; *see also* Wall Letter.

[26] Steiner Letter.

[27] *See* FINRA Letter at 2.

[28] *See id.*

[29] *See id.*

[30] *See* PIABA Letter and SIFMA Letter.

[31] *See* PIABA Letter at 3.

[32] *See* FINRA Letter at 2.

[33] *See* SIFMA Letter at 2.

[34] *See id.*

[35] *See id.*

[36] *See* FINRA Letter at 3–4.

[37] In approving this rule change, the Commission has considered the rule's impact on efficiency, competition, and capital formation. *See* 15 U.S.C. 78c(f).

[38] 15 U.S.C. 78o–3(b)(6).

The Commission notes that six commenters were generally supportive of the proposal. One of those commenters recommended FINRA amend the proposal to clarify the intent of the proposal—that it was meant to address all payments ordered made to opposing parties in an arbitration and not just damages[42]—and FINRA agreed.[43] The Commission further notes that one of the commenters that generally supported the proposal also recommended that FINRA implement a national recovery pool for unpaid arbitration awards,[44] which the Commission believes is outside the scope of the current proposal.

The Commission recognizes two commenters' objections to the proposal on the basis that a default in favor of award offsets is not necessary because the parties may already request offsets.[45] The Commission also recognizes, however, FINRA's belief that the proposal will "eliminate ambiguity," "reduce the risk of post-award disputes," and "likely reduce legal expenses to the party owed greater damages by eliminating the need to apply for the reopening of the case or going to court to seek award offsets, or seek other redress."[46] The Commission further recognizes, as FINRA pointed out in its response, that the proposal "does not override arbitrator discretion."[47] Arbitrators are thus still free to decline to offset awards if they deem it inappropriate.

Taking into consideration the comments and FINRA's response and proposed amendment, the Commission believes that the proposal is consistent with the Exchange Act. The Commission believes that the proposal will help protect investors and the public interest by streamlining the payment of arbitration awards in instances where parties are ordered to make payments to one another, without overriding arbitrator discretion. The Commission further believes that FINRA's response, as discussed in more detail above, appropriately addressed commenters' concerns and adequately explained its reasons for modifying its proposal to clarify that the default in favor of award offsets would apply to all awards however characterized by the arbitrator. The Commission believes that the approach proposed by FINRA is appropriate and designed to protect investors and the public interest, consistent with section 15A(b)(6) of the Exchange Act. For these reasons, the Commission finds that the proposed rule change is consistent with the Exchange Act and the rules and regulations thereunder.

V. Solicitation of Comments on Amendment No. 1 to the Proposed Rule Change

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposal, as modified by Amendment No. 1, is consistent with the Exchange Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–FINRA–2016–015 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–FINRA–2016–015. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549–1090, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of such filing will also be available for inspection and copying at the principal office of FINRA. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–FINRA–2016–015 and should be submitted on or before September 7, 2016.

VI. Accelerated Approval of Proposed Rule Change, as Modified by Amendment No. 1

The Commission finds good cause to approve the proposed rule change, as modified by Amendment No. 1, prior to the thirtieth day after the date of publication of notice of the amended proposal in the **Federal Register**. The revisions made to the proposal in Amendment No. 1 changed how amounts ordered by arbitrators to be paid to opposing parties would be calculated for purposes of offsetting payments to one another. In particular, the proposed amendment would effectively replace the word "damages" with "payments" in order to capture those portions of awards attributable to amounts other than damages (*e.g.*, costs and fees).[48] The Commission believes that this modification responds to one of the primary concerns raised by commenters on the proposal that the proposal was never intended to be strictly limited to offsetting "damages."[49] Therefore, the Commission believes that the proposed amendment clarifies the intent of the proposal.

Accordingly, the Commission finds good cause, pursuant to section 19(b)(2) of the Exchange Act,[50] to approve the proposed rule change, as modified by Amendment No. 1, on an accelerated basis.

VII. Conclusion

IT IS THEREFORE ORDERED pursuant to section 19(b)(2)[51] of the Exchange Act that the proposal (SR–FINRA–2016–015), as modified by Amendment No. 1, be and hereby is approved on an accelerated basis.

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[39] Notice at 32360.

[40] *Id.*

[41] *Id.*

[42] *See* SIFMA Letter.

[43] *See* FINRA Letter.

[44] *See* PIABA Letter.

[45] *See* Steiner Letter; *see also* Wall Letter.

[46] *See* FINRA Letter at 2.

[47] *See id.*

[48] *See* FINRA Letter; *see also* proposed FINRA Rules 12904(j) and 13904(j).

[49] *See* SIFMA Letter; *see all* FINRA Letters.

[50] 15 U.S.C. 78s(b)(2).

[51] *Id.*

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[52]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19587 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78543; File No. SR–BatsBZX–2016–45]

Self-Regulatory Organizations; Bats BZX Exchange, Inc.; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change Related to Logical Port Fees

August 11, 2016.

Pursuant to Section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"),[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on July 29, 2016, Bats BZX Exchange, Inc. (the "Exchange" or "BZX") filed with the Securities and Exchange Commission ("Commission") the proposed rule change as described in Items I, II and III below, which Items have been prepared by the Exchange. The Exchange has designated the proposed rule change as one establishing or changing a member due, fee, or other charge imposed by the Exchange under Section 19(b)(3)(A)(ii) of the Act[3] and Rule 19b–4(f)(2) thereunder,[4] which renders the proposed rule change effective upon filing with the Commission. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange filed a proposal to amend the fee schedule applicable to Members[5] and non-Members of the Exchange pursuant to BZX Rules 15.1(a) and (c).

The text of the proposed rule change is available at the Exchange's Web site at *www.batstrading.com*, at the principal office of the Exchange, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in Sections A, B, and C below, of the most significant parts of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend its fee schedule to modify the billing policy for the logical port fees. The Exchange currently charges for logical ports (including Multicast PITCH Spin Server and GRP ports) $500 per port per month. A logical port represents a port established by the Exchange within the Exchange's system for trading and billing purposes. Each logical port established is specific to a Member or non-Member and grants that Member or non-Member the ability to operate a specific application, such as FIX order entry or PITCH data receipt. The Exchange's Multicast PITCH data feed is available from two primary feeds, identified as the "A feed" and the "C feed", which contain the same information but differ only in the way such feeds are received. The Exchange also offers two redundant feeds, identified as the "B feed" and the "D feed". Logical port fees are limited to logical ports in the Exchange's primary data center and no logical port fees are assessed for redundant secondary data center ports. The Exchange assesses the monthly per logical port fees to all Member's and non-Member's logical ports.

The Exchange proposes to clarify within its fee schedule how monthly fees for logical ports may be pro-rated. As proposed, new requests will be pro-rated for the first month of service. Cancellation requests are billed in full month increments as firms are required to pay for the service for the remainder of the month, unless the session is terminated within the first month of service.

Implementation Date

The Exchange proposes to implement these amendments to its fee schedule on August 1, 2016.

2. Statutory Basis

The Exchange believes that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder that are applicable to a national securities exchange, and, in particular, with the requirements of Section 6 of the Act.[6] Specifically, the Exchange believes that the proposed rule change is consistent with Section 6(b)(4) of the Act,[7] in that it provides for the equitable allocation of reasonable dues, fees and other charges among members and other persons using any facility or system which the Exchange operates or controls. The proposed rule change seeks to provide clarity to subscribers regarding the Exchange's pro-rata billing policy for logical ports by describing how logical port fees may be pro-rated for a new request and upon cancellation. The Exchange believes that the proposed pro-rata billing of fees for logical ports is reasonable in that it is similar to how port fees are pro-rated by the Nasdaq Stock Market LLC ("Nasdaq").[8]

The Exchange operates in a highly competitive market in which exchanges offer connectivity services as a means to facilitate the trading activities of Members and other participants. Accordingly, fees charged for connectivity are constrained by the active competition for the order flow of such participants as well as demand for market data from the Exchange. If a particular exchange charges excessive fees for connectivity, affected Members will opt to terminate their connectivity arrangements with that exchange, and adopt a possible range of alternative strategies, including routing to the applicable exchange through another participant or market center or taking that exchange's data indirectly. Accordingly, an exchange charging excessive fees would stand to lose not only connectivity revenues, but also revenues associated with the execution of orders routed to it by affected members, and, to the extent applicable, market data revenues. The Exchange believes that this competitive dynamic imposes powerful restraints on the ability of any exchange to charge unreasonable fees for connectivity.

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[52] 17 CFR 200.30–3(a)(12).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(ii).

[4] 17 CFR 240.19b–4(f)(2).

[5] The term "Member" is defined as "any registered broker or dealer that has been admitted to membership in the Exchange." *See* Exchange Rule 1.5(n).

[6] 15 U.S.C. 78f.

[7] 15 U.S.C. 78f(b)(4).

[8] *See* Nasdaq Price List—Trade Connectivity *available at http://www.nasdaqtrader.com/Trader.aspx?id=PriceListTrading2#connectivity.* The Exchange notes that, unlike as proposed by the Exchange, Nasdaq does not pro-rate where the session is terminated within the first month of service.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes its proposed amendment to its fee schedule would not impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act in that it is simply designed to set forth the Exchange's pro-rata billing for logical ports and is similar to that currently offered by one of the Exchange's competitors.[9] Members may opt to disfavor the Exchange's pricing if they believe that alternatives offer them better value. Accordingly, the Exchange does not believe that the proposed change will impair the ability of Members or competing venues to maintain their competitive standing in the financial markets.

The Exchange believes that fees for connectivity are constrained by the robust competition for order flow among exchanges and non-exchange markets. Further, excessive fees for connectivity, including logical port fees, would serve to impair an exchange's ability to compete for order flow rather than burdening competition. The Exchange also does not believe the proposed rule change would impact intramarket competition as it would apply to all Members and non-Members equally.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

The Exchange has not solicited, and does not intend to solicit, comments on this proposed rule change. The Exchange has not received any written comments from members or other interested parties.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

The foregoing rule change has become effective pursuant to Section 19(b)(3)(A) of the Act[10] and paragraph (f) of Rule 19b–4 thereunder.[11] At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File Number SR–BatsBZX–2016–45 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–BatsBZX–2016–45. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–BatsBZX–2016–45, and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[12]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19574 Filed 8–16–16; 8:45 am]

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[9] *Id.*

[10] 15 U.S.C. 78s(b)(3)(A).

[11] 17 CFR 240.19b–4(f).

[12] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78552; File No. 4–618]

Program for Allocation of Regulatory Responsibilities Pursuant to Rule 17d–2; Notice of Filing and Order Approving and Declaring Effective an Amendment to the Plan for the Allocation of Regulatory Responsibilities Between Bats BZX Exchange, Inc., Bats BYX Exchange, Inc., BOX Options Exchange LLC, Chicago Board Options Exchange, Incorporated, C2 Options Exchange, Incorporated, Chicago Stock Exchange, Inc., Bats EDGA Exchange, Inc., Bats EDGX Exchange, Inc., Financial Industry Regulatory Authority, Inc., International Securities Exchange, LLC, Investors Exchange LLC, ISE Gemini, LLC, ISE Mercury, LLC, Miami International Securities Exchange, LLC, The NASDAQ Stock Market LLC, NASDAQ BX, Inc., NASDAQ PHLX, Inc., National Stock Exchange, Inc., New York Stock Exchange LLC, NYSE MKT LLC, and NYSE Arca, Inc.

August 11, 2016.

Notice is hereby given that the Securities and Exchange Commission ("Commission") has issued an Order, pursuant to Section 17(d) of the Securities Exchange Act of 1934 ("Act"),[1] approving and declaring effective an amendment to the plan for allocating regulatory responsibility ("Plan") filed on August 4, 2016, pursuant to Rule 17d–2 of the Act,[2] by Bats BZX Exchange, Inc. ("BATS"), Bats BYX Exchange, Inc. ("BATS Y"), BOX Options Exchange LLC ("BOX"), Chicago Board Options Exchange, Incorporated ("CBOE"), C2 Options Exchange, Incorporated ("C2"), Chicago Stock Exchange, Inc. ("CHX"), Bats EDGA Exchange, Inc. ("EDGA"), Bats EDGX Exchange, Inc. ("EDGX"), Financial Industry Regulatory Authority, Inc. ("FINRA"), International Securities Exchange, LLC ("ISE"), Investors Exchange LLC ("IEX"), ISE Gemini, LLC ("ISE Gemini"), ISE Mercury, LLC ("ISE Mercury"), Miami

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[1] 15 U.S.C. 78q(d).

[2] 17 CFR 240.17d–2.

International Securities Exchange, LLC ("MIAX"), The NASDAQ Stock Market LLC ("NASDAQ"), NASDAQ BX, Inc. ("BX"), NASDAQ PHLX, Inc. ("Phlx"), National Stock Exchange, Inc. ("NSX"), New York Stock Exchange LLC ("NYSE"), NYSE MKT LLC ("NYSE MKT"), and NYSE Arca, Inc. ("NYSE Arca") (each, a "Participating Organization," and, together, the "Participating Organizations" or the "Parties"). As further discussed in Section III, below, this Agreement amends and restates the agreement by and among the Participating Organizations approved by the SEC on October 29, 2015.[3]

I. Introduction

Section 19(g)(1) of the Act,[4] among other things, requires every self-regulatory organization ("SRO") registered as either a national securities exchange or national securities association to examine for, and enforce compliance by, its members and persons associated with its members with the Act, the rules and regulations thereunder, and the SRO's own rules, unless the SRO is relieved of this responsibility pursuant to Section 17(d) or Section 19(g)(2) of the Act.[5] Without this relief, the statutory obligation of each individual SRO could result in a pattern of multiple examinations of broker-dealers that maintain memberships in more than one SRO ("common members"). Such regulatory duplication would add unnecessary expenses for common members and their SROs.

Section 17(d)(1) of the Act[6] was intended, in part, to eliminate unnecessary multiple examinations and regulatory duplication.[7] With respect to a common member, Section 17(d)(1) authorizes the Commission, by rule or order, to relieve an SRO of the responsibility to receive regulatory reports, to examine for and enforce compliance with applicable statutes, rules, and regulations, or to perform other specified regulatory functions.

To implement Section 17(d)(1), the Commission adopted two rules: Rule 17d–1 and Rule 17d–2 under the Act.[8] Rule 17d–1 authorizes the Commission to name a single SRO as the designated examining authority ("DEA") to examine common members for compliance with the financial responsibility requirements imposed by the Act, or by Commission or SRO rules.[9] When an SRO has been named as a common member's DEA, all other SROs to which the common member belongs are relieved of the responsibility to examine the firm for compliance with the applicable financial responsibility rules. On its face, Rule 17d–1 deals only with an SRO's obligations to enforce member compliance with financial responsibility requirements. Rule 17d–1 does not relieve an SRO from its obligation to examine a common member for compliance with its own rules and provisions of the federal securities laws governing matters other than financial responsibility, including sales practices and trading activities and practices.

To address regulatory duplication in these and other areas, the Commission adopted Rule 17d–2 under the Act.[10] Rule 17d–2 permits SROs to propose joint plans for the allocation of regulatory responsibilities with respect to their common members. Under paragraph (c) of Rule 17d–2, the Commission may declare such a plan effective if, after providing for appropriate notice and comment, it determines that the plan is necessary or appropriate in the public interest and for the protection of investors; to foster cooperation and coordination among the SROs; to remove impediments to, and foster the development of, a national market system and a national clearance and settlement system; and is in conformity with the factors set forth in Section 17(d) of the Act. Commission approval of a plan filed pursuant to Rule 17d–2 relieves an SRO of those regulatory responsibilities allocated by the plan to another SRO.

II. The Plan

On December 3, 2010, the Commission approved the SRO participants' plan for allocating regulatory responsibilities pursuant to Rule 17d–2.[11] On October 29, 2015, the Commission approved an amended plan that added Regulation NMS Rules 606, 607, and 611(c) and (d) and added additional Participating Organizations that are options markets to the Plan.[12]

The proposed 17d–2 Plan is intended to reduce regulatory duplication for firms that are members of more than one Participating Organization.[13] The Plan provides for the allocation of regulatory responsibility according to whether the covered rule pertains to NMS stocks or NMS securities. For covered rules that pertain to NMS stocks (*i.e.,* Rules 607, 611, and 612), FINRA serves as the "Designated Regulation NMS Examining Authority" ("DREA") for common members that are members of FINRA, and assumes certain examination and enforcement responsibilities for those members with respect to specified Regulation NMS rules. For common members that are not members of FINRA, the member's DEA serves as the DREA, provided that the DEA exchange operates a national securities exchange or facility that trades NMS stocks and the common member is a member of such exchange or facility. Section 1(c) of the Plan contains a list of principles that are applicable to the allocation of common members in cases not specifically addressed in the Plan. An exchange that does not trade NMS stocks would have no regulatory authority for covered Regulation NMS rules pertaining to NMS stocks. For covered rules that pertain to NMS securities, and thus include options (*i.e.,* Rule 606), the Plan provides that the DREA will be the same as the DREA for the rules pertaining to NMS stocks. For common members that are not members of an exchange that trades NMS stocks, the common member would be allocated according to the principles set forth in Section 1(c) of the Plan.

The text of the Plan delineates the proposed regulatory responsibilities with respect to the Parties. Included in the proposed Plan is an exhibit (the "Covered Regulation NMS Rules") that lists the federal securities laws, rules, and regulations, for which the applicable DREA would bear examination and enforcement responsibility under the Plan for common members of the Participating Organization and their associated persons.

Specifically, the applicable DREA assumes examination and enforcement responsibility relating to compliance by common members with the Covered Regulation NMS Rules. Covered Regulation NMS Rules do not include the application of any rule of a Participating Organization, or any rule or regulation under the Act, to the extent that it pertains to violations of insider trading activities, because such matters are covered by a separate multiparty agreement under Rule 17d–2.[14] Under the Plan, Participating Organizations retain full responsibility for surveillance and enforcement with respect to trading activities or practices involving their own marketplace.[15]

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[3] *See* Securities Exchange Act Release No. 76311, 80 FR 68377 (November 4, 2015).

[4] 15 U.S.C. 78s(g)(1).

[5] 15 U.S.C. 78q(d) and 15 U.S.C. 78s(g)(2), respectively.

[6] 15 U.S.C. 78q(d)(1).

[7] *See* Securities Act Amendments of 1975, Report of the Senate Committee on Banking, Housing, and Urban Affairs to Accompany S. 249, S. Rep. No. 94–75, 94th Cong., 1st Session 32 (1975).

[8] 17 CFR 240.17d–1 and 17 CFR 240.17d–2, respectively.

[9] *See* Securities Exchange Act Release No. 12352 (April 20, 1976), 41 FR 18808 (May 7, 1976).

[10] *See* Securities Exchange Act Release No. 12935 (October 28, 1976), 41 FR 49091 (November 8, 1976).

[11] *See* Securities Exchange Act Release No. 63430, 75 FR 76758 (December 9, 2010).

[12] *See* Securities Exchange Act Release No. 76311, 80 FR 68377 (November 4, 2015).

[13] The proposed 17d–2 Plan refers to these members as "Common Members."

III. Proposed Amendment to the Plan

On August 4, 2016, the parties submitted a proposed amendment to the Plan. The primary purpose of the amendment is to add IEX and ISE Mercury as Participants to the Plan and to reflect name changes of certain Participating Organizations.

The text of the proposed amended 17d–2 Plan is as follows (additions are in italics; deletions are in brackets):

* * * * *

Agreement for the Allocation of Regulatory Responsibility for the Covered Regulation NMS Rules Pursuant to § 17(d) of the Securities Exchange Act of 1934, 15 U.S.C. 78q(d), and Rule 17d–2 Thereunder

This agreement (the "Agreement") by and among [BATS]*Bats BZX* Exchange, Inc. ("BATS"), [BATS Y–]*Bats BYX* Exchange, Inc. ("BATS Y"), BOX Options Exchange LLC ("BOX"), Chicago Board Options Exchange, Incorporated ("CBOE"), C2 Options Exchange, Incorporated ("C2"), Chicago Stock Exchange, Inc. ("CHX"), *Bats* EDGA Exchange, Inc. ("EDGA"), *Bats* EDGX Exchange, Inc. ("EDGX"), Financial Industry Regulatory Authority, Inc. ("FINRA"), International Securities Exchange, LLC ("ISE"), ISE Gemini, LLC ("ISE Gemini"), *ISE Mercury, LLC ("ISE Mercury"), Investors Exchange LLC ("IEX"),* Miami International Securities Exchange, LLC ("MIAX"), The NASDAQ Stock Market LLC ("NASDAQ"), NASDAQ [OMX] BX, Inc. *("BX"),* NASDAQ [OMX] PHLX, Inc. *("PHLX"),* National Stock Exchange, Inc. ("NSX"), New York Stock Exchange LLC ("NYSE"), NYSE MKT LLC ("NYSE MKT"), and NYSE Arca, Inc. ("NYSE Arca") (each, a "Participating Organization," and, together, the "Participating Organizations"), is made pursuant to § 17(d) of the Securities Exchange Act of 1934 (the "Act" or "SEA"), 15 U.S.C. 78q(d), and Rule 17d–2 thereunder, which allow for plans to allocate regulatory responsibility among self-regulatory organizations ("SROs"). Upon approval by the Securities and Exchange Commission ("Commission" or "SEC"), this Agreement shall amend and restate the agreement by and among the Participating Organizations approved by the SEC on [December 3, 2010] *October 29, 2015.*

WHEREAS, the Participating Organizations desire to: (a) Foster cooperation and coordination among the SROs; (b) remove impediments to, and foster the development of, a national market system; (c) strive to protect the interest of investors; and (d) eliminate duplication in their examination and enforcement of SEA Rules 606, 607, 611 and 612 (the "Covered Regulation NMS Rules");

WHEREAS, the Participating Organizations are interested in allocating regulatory responsibilities with respect to broker-dealers that are members of more than one Participating Organization (the "Common Members") relating to the examination and enforcement of the Covered Regulation NMS Rules; and

WHEREAS, the Participating Organizations will request regulatory allocation of these regulatory responsibilities by executing and filing with the SEC this plan for the above stated purposes pursuant to the provisions of § 17(d) of the Act, and Rule 17d–2 thereunder, as described below.

NOW, THEREFORE, in consideration of the mutual covenants contained hereafter, and other valuable consideration to be mutually exchanged, the Participating Organizations hereby agree as follows:

1. *Assumption of Regulatory Responsibility.* The Designated Regulation NMS Examining Authority (the "DREA") shall assume examination and enforcement responsibilities relating to compliance by Common Members with the Covered Regulation NMS Rules to which the DREA is allocated responsibility ("Regulatory Responsibility"). A list of the Covered Regulation NMS Rules is attached hereto as Exhibit A.

a. For Covered Regulation NMS Rules Pertaining to "NMS stocks" (as defined in Regulation NMS) (*i.e.,* Rules 607, 611 and 612): FINRA shall serve as DREA for Common Members that are members of FINRA. The Designated Examining Authority ("DEA") pursuant to SEA Rule 17d–1 shall serve as DREA for Common Members that are not members of FINRA, provided that the DEA operates a national securities exchange or facility that trades NMS stocks and the Common Member is a member of such exchange or facility. For all other Common Members, the Participating Organizations shall allocate Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS stocks based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member. (A Participating Organization that operates a national securities exchange that does not trade NMS stocks has no regulatory responsibilities related to Covered Regulation NMS Rules pertaining to NMS stocks and will not serve as DREA for such Covered Regulation NMS Rules.)

b. For Covered Regulation NMS Rules Pertaining to "NMS securities" (as defined in Regulation NMS) (*i.e.,* Rule 606), the DREA shall be same as the DREA for Covered Regulation NMS Rules pertaining to NMS stocks. For Common Members that are not members of a national securities exchange that trades NMS stocks and thus have not been appointed a DREA under paragraph a., the Participating Organizations shall allocate the Common Members among the Participating Organizations (other than FINRA) that operate a national securities exchange that trades NMS securities based on the principles outlined below and the Participating Organization to which such a Common Member is allocated shall serve as the DREA for that Common Member with respect to Covered Regulation NMS Rules pertaining to NMS securities. The allocation of Common Members to DREAs (including FINRA) for all Covered Regulation NMS Rules is provided in Exhibit B.

c. For purposes of this paragraph 1, any allocation of a Common Member to a Participating Organization other than as specified in paragraphs a. and b. above shall be based on the following principles, except to the extent all affected Participating Organizations consent to one or more different principles and any such agreement to different principles would be deemed an amendment to this Agreement as provided in paragraph 22:

i. The Participating Organizations shall not allocate a Common Member to a Participating Organization unless the Common Member is a member of that Participating Organization.

ii. To the extent practicable, Common Members shall be allocated among the Participating Organizations of which they are members in such a manner as to equalize, as nearly as possible, the allocation among such Participating Organizations.

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[14] *See* Securities Exchange Act Release No. 58350 (August 13, 2008), 73 FR 48247 (August 18, 2008) (File No. 4–566) (notice of filing of proposed plan). *See also* Securities Exchange Act Release No. 58536 (September 12, 2008) (File No. 4–566) (order approving and declaring effective the plan).

[15] *See* paragraph 1 of the proposed 17d–2 Plan.

iii. To the extent practicable, the allocation will take into account the amount of NMS stock activity (or NMS security activity, as applicable) conducted by each Common Member in order to most evenly divide the Common Members with the largest amount of activity among the Participating Organizations of which they are a members. The allocation will also take into account similar allocations pursuant to other plans or agreements to which the Participating Organizations are party to maintain consistency in oversight of the Common Members.[1]

iv. The Participating Organizations may reallocate Common Members from time-to-time and in such manner as they deem appropriate consistent with the terms of this Agreement.

v. Whenever a Common Member ceases to be a member of its DREA (including FINRA), the DREA shall promptly inform the Participating Organizations, who shall review the matter and reallocate the Common Member to another Participating Organization.

vi. The DEA or DREA (including FINRA) may request that a Common Member be reallocated to another Participating Organization (including the DEA or DREA (including FINRA)) by giving 30 days written notice to the Participating Organizations. The Participating Organizations shall promptly consider such request and, in their discretion, may approve or disapprove such request and if approved, reallocate the Common Member to such Participating Organization.

vii. All determinations by the Participating Organizations with respect to allocations shall be by the affirmative vote of a majority of the Participating Organizations that, at the time of such determination, share the applicable Common Member being allocated; a Participating Organization shall not be entitled to vote on any allocation related to a Common Member unless the Common Member is a member of such Participating Organization.

d. The Participating Organizations agree that they shall conduct meetings among them as needed for the purposes of ensuring proper allocation of Common Members and identifying issues or concerns with respect to the regulation of Common Members. Notwithstanding anything herein to the contrary, it is explicitly understood that the term "Regulatory Responsibility" does not include, and each of the Participating Organizations shall retain full responsibility for, examination, surveillance and enforcement with respect to trading activities or practices involving its own marketplace unless otherwise allocated pursuant to a separate Rule 17d–2 Agreement.

2. *No Retention of Regulatory Responsibility.* The Participating Organizations do not contemplate the retention of any responsibilities with respect to the regulatory activities being assumed by the DREA under the terms of this Agreement. Nothing in this Agreement will be interpreted to prevent a DREA from entering into Regulatory Services Agreement(s) to perform its Regulatory Responsibility.

3. *No Charge.* A DREA shall not charge Participating Organizations for performing the Regulatory Responsibility under this Agreement.

4. *Applicability of Certain Laws, Rules, Regulations or Orders.* Notwithstanding any provision hereof, this Agreement shall be subject to any statute, or any rule or order of the SEC. To the extent such statute, rule, or order is inconsistent with one or more provisions of this Agreement, the statute, rule, or order shall supersede the provision(s) hereof to the extent necessary to be properly effectuated and the provision(s) hereof in that respect shall be null and void.

5. *Customer Complaints.* If a Participating Organization receives a copy of a customer complaint relating to a DREA's Regulatory Responsibility as set forth in this Agreement, the Participating Organization shall promptly forward to such DREA a copy of such customer complaint. It shall be such DREA's responsibility to review and take appropriate action in respect to such complaint.

6. *Parties to Make Personnel Available as Witnesses.* Each Participating Organization shall make its personnel available to the DREA to serve as testimonial or non-testimonial witnesses as necessary to assist the DREA in fulfilling the Regulatory Responsibility allocated under this Agreement. The DREA shall provide reasonable advance notice when practicable and shall work with a Participating Organization to accommodate reasonable scheduling conflicts within the context and demands as the entity with ultimate regulatory responsibility. The Participating Organization shall pay all reasonable travel and other expenses incurred by its employees to the extent that the DREA requires such employees to serve as witnesses, and provide information or other assistance pursuant to this Agreement.

7. *Sharing of Work-Papers, Data and Related Information.*

a. *Sharing.* A Participating Organization shall make available to the DREA information necessary to assist the DREA in fulfilling the Regulatory Responsibility assumed under the terms of this Agreement. Such information shall include *any* information collected by a Participating Organization in the course of performing its regulatory obligations under the Act, including information relating to an on-going disciplinary investigation or action against a member, the amount of a fine imposed on a member, financial information, or information regarding proprietary trading systems gained in the course of examining a member ("Regulatory Information"). This Regulatory Information shall be used by the DREA solely for the purposes of fulfilling the DREA's Regulatory Responsibility.

b. *No Waiver of Privilege.* The sharing of documents or information between the parties pursuant to this Agreement shall not be deemed a waiver as against third parties of regulatory or other privileges relating to the discovery of documents or information.

8. *Special or Cause Examinations and Enforcement Proceedings.* Nothing in this Agreement shall restrict or in any way encumber the right of a Participating Organization to conduct special or cause examinations of a Common Member, or take enforcement proceedings against a Common Member as a Participating Organization, in its sole discretion, shall deem appropriate or necessary.

9. *Dispute Resolution Under This Agreement.*

a. *Negotiation.* The Participating Organizations will attempt to resolve any disputes through good faith negotiation and discussion, escalating such discussion up through the appropriate management levels until reaching the executive management level. In the event a dispute cannot be settled through these means, the Participating Organizations shall refer the dispute to binding arbitration.

b. *Binding Arbitration.* All claims, disputes, controversies, and other matters in question between the Participating Organizations to this Agreement arising out of or relating to this Agreement or the breach thereof that cannot be resolved by the Participating Organizations will be resolved through binding arbitration.

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[1] For example, if one Participating Organization was allocated responsibility for a particular Common Member pursuant to a separate Rule 17d–2 Agreement, that Participant Organization would be assigned to be the DREA of that Common Member, unless there is good cause not to make that assignment.

Unless otherwise agreed by the Participating Organizations, a dispute submitted to binding arbitration pursuant to this paragraph shall be resolved using the following procedures:

(i) The arbitration shall be conducted in a city selected by the DREA in which it maintains a principal office or where otherwise agreed to by the Participating Organizations in accordance with the Commercial Arbitration Rules of the American Arbitration Association and judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction thereof; and

(ii) There shall be three arbitrators, and the chairperson of the arbitration panel shall be an attorney. The arbitrators shall be appointed in accordance with the Commercial Arbitration Rules of the American Arbitration Association.

10. *Limitation of Liability.* As between the Participating Organizations, no Participating Organization, including its respective directors, governors, officers, employees and agents, will be liable to any other Participating Organization, or its directors, governors, officers, employees and agents, for any liability, loss or damage resulting from any delays, inaccuracies, errors or omissions with respect to its performing or failing to perform regulatory responsibilities, obligations, or functions, except: (a) As otherwise provided for under the Act; (b) in instances of a Participating Organization's gross negligence, willful misconduct or reckless disregard with respect to another Participating Organization; or (c) in instances of a breach of confidentiality obligations owed to another Participating Organization. The Participating Organizations understand and agree that the regulatory responsibilities are being performed on a good faith and best effort basis and no warranties, express or implied, are made by any Participating Organization to any other Participating Organization with respect to any of the responsibilities to be performed hereunder. This paragraph is not intended to create liability of any Participating Organization to any third party.

11. *SEC Approval.*

a. The Participating Organizations agree to file promptly this Agreement with the SEC for its review and approval. FINRA shall file this Agreement on behalf, and with the explicit consent, of all Participating Organizations.

b. If approved by the SEC, the Participating Organizations will notify their members of the general terms of the Agreement and of its impact on their members.

12. *Subsequent Parties; Limited Relationship.* This Agreement shall inure to the benefit of and shall be binding upon the Participating Organizations hereto and their respective legal representatives, successors, and assigns. Nothing in this Agreement, expressed or implied, is intended or shall: (a) Confer on any person other than the Participating Organizations hereto, or their respective legal representatives, successors, and assigns, any rights, remedies, obligations or liabilities under or by reason of this Agreement, (b) constitute the Participating Organizations hereto partners or participants in a joint venture, or (c) appoint one Participating Organization the agent of the other.

13. *Assignment.* No Participating Organization may assign this Agreement without the prior written consent of the DREAs performing Regulatory Responsibility on behalf of such Participating Organization, which consent shall not be unreasonably withheld, conditioned or delayed; provided, however, that any Participating Organization may assign the Agreement to a corporation controlling, controlled by or under common control with the Participating Organization without the prior written consent of such Participating Organization's DREAs. No assignment shall be effective without Commission approval.

14. *Severability.* Any term or provision of this Agreement that is invalid or unenforceable in any jurisdiction shall, as to such jurisdiction, be ineffective to the extent of such invalidity or unenforceability without rendering invalid or unenforceable the remaining terms and provisions of this Agreement or affecting the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction.

15. *Termination.* Any Participating Organization may cancel its participation in the Agreement at any time upon the approval of the Commission after 180 days written notice to the other Participating Organizations (or in the case of a change of control in ownership of a Participating Organization, such other notice time period as that Participating Organization may choose). The cancellation of its participation in this Agreement by any Participating Organization shall not terminate this Agreement as to the remaining Participating Organizations.

16. *General.* The Participating Organizations agree to perform all acts and execute all supplementary instruments or documents that may be reasonably necessary or desirable to carry out the provisions of this Agreement.

17. *Written Notice.* Any written notice required or permitted to be given under this Agreement shall be deemed given if sent by certified mail, return receipt requested, or by a comparable means of electronic communication to each Participating Organization entitled to receipt thereof, to the attention of the Participating Organization's representative at the Participating Organization's then principal office or by email.

18. *Confidentiality.* The Participating Organizations agree that documents or information shared shall be held in confidence, and used only for the purposes of carrying out their respective regulatory obligations under this Agreement, provided, however, that each Participating Organization may disclose such documents or information as may be required to comply with applicable requlatory requirements or requests for information from the SEC. Any Participating Organization disclosing confidential documents or information in compliance with applicable regulatory or oversight requirements will request confidential treatment of such information. No Participating Organization shall assert regulatory or other privileges as against the other with respect to Regulatory Information that is required to be shared pursuant to this Agreement.

19. *Regulatory Responsibility.* Pursuant to Section 17(d)(1)(A) of the Act, and Rule 17d–2 thereunder, the Participating Organizations request the SEC, upon its approval of this Agreement, to relieve the Participating Organizations which are participants in this Agreement that are not the DREA as to a Common Member of any and all responsibilities with respect to the matters allocated to the DREA pursuant to this Agreement for purposes of §§ 17(d) and 19(g) of the Act.

20. *Governing Law.* This Agreement shall be deemed to have been made in the State of New York, and shall be construed and enforced in accordance with the law of the State of New York, without reference to principles of conflicts of laws thereof. Each of the Participating Organizations hereby consents to submit to the jurisdiction of the courts of the State of New York in connection with any action or proceeding relating to this Agreement.

21. *Survival of Provisions.* Provisions intended by their terms or context to survive and continue notwithstanding delivery of the regulatory services by the

DREA and any expiration of this Agreement shall survive and continue.

22. *Amendment.*

a. This Agreement may be amended to add a new Participating Organization, provided that such Participating Organization does not assume regulatory responsibility, by an amendment executed by all applicable DREAs and such new Participating Organization. All other Participating Organizations expressly consent to allow such DREAs to jointly add new Participating Organizations to the Agreement as provided above. Such DREAs will promptly notify all Participating Organizations of any such amendments to add a new Participating Organization.

b. All other amendments must be approved by each Participating Organization. All amendments, including adding a new Participating Organization but excluding changes to Exhibit B, must be filed with and approved by the Commission before they become effective.

23. *Effective Date.* The Effective Date of this Agreement will be the date the SEC declares this Agreement to be effective pursuant to authority conferred by § 17(d) of the Act, and Rule 17d–2 thereunder.

24. *Counterparts.* This Agreement may be executed in any number of counterparts, including facsimile, each of which will be deemed an original, but all of which taken together shall constitute one single agreement among the Participating Organizations.

* * * * *

Exhibit A

Covered Regulation NMS Rules

SEA Rule 606—Disclosure of Order Routing Information.*
SEA Rule 607—Customer Account Statements.
SEA Rule 611—Order Protection Rule.
SEA Rule 612—Minimum Pricing Increment.

* Covered Regulation NMS Rules with asterisks (*) pertain to NMS securities. Covered Regulation NMS Rules without asterisks pertain to NMS stocks.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml);* or
- Send an email to *rule-comments@sec.gov.* Please include File Number 4–618 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number 4–618. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed plan that are filed with the Commission, and all written communications relating to the proposed plan between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the plan also will be available for inspection and copying at the principal offices of the Participating Organizations. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number 4–618 and should be submitted on or before September 7, 2016.

V. Discussion

The Commission finds that the Plan, as amended, is consistent with the factors set forth in Section 17(d) of the Act[16] and Rule 17d–2(c) thereunder[17] in that the proposed amended Plan is necessary or appropriate in the public interest and for the protection of investors, fosters cooperation and coordination among SROs, and removes impediments to and fosters the development of the national market system. In particular, the Commission believes that the proposed amended Plan should reduce unnecessary regulatory duplication by allocating to the applicable DREA certain examination and enforcement responsibilities for Common Members that would otherwise be performed by multiple Parties. Accordingly, the proposed amended Plan promotes efficiency by reducing costs to Common Members. Furthermore, because the Parties will coordinate their regulatory functions in accordance with the proposed amended Plan, the amended Plan should promote investor protection.

The Commission is hereby declaring effective a plan that allocates regulatory responsibility for certain provisions of the federal securities laws, rules, and regulations as set forth in Exhibit A to the Plan. The Commission notes that any amendment to the Plan must be approved by the relevant Parties as set forth in Paragraph 22 of the Plan and must be filed with and approved by the Commission before it may become effective.[18]

Under paragraph (c) of Rule 17d–2, the Commission may, after appropriate notice and comment, declare a plan, or any part of a plan, effective. In this instance, the Commission believes that appropriate notice and comment can take place after the proposed amendment is effective. In particular, the purpose of the amendment is to add IEX and ISE Mercury as Participating Organizations and to reflect name changes of certain Participating Organizations. The Commission notes that the most recent prior amendment to the Plan was published for comment and the Commission did not receive any comments thereon.[19] The Commission believes that the current amendment to the Plan does not raise any new regulatory issues that the Commission has not previously considered, and therefore believes that the amended Plan should become effective without any undue delay.

VI. Conclusion

This order gives effect to the amended Plan filed with the Commission that is contained in File No. 4–618.

IT IS THEREFORE ORDERED, pursuant to Section 17(d) of the Act, that the Plan, as amended, filed with the Commission pursuant to Rule 17d–2 on August 4, 2016, is hereby approved and declared effective.

IT IS FURTHER ORDERED that those SRO participants that are not the DREA as to a particular common member are relieved of those regulatory responsibilities allocated to the common member's DREA under the amended Plan to the extent of such allocation.

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[16] 15 U.S.C. 78q(d).

[17] 17 CFR 240.17d–2(c).

[18] *See* Paragraph 22 of the Plan. The Commission notes, however, that changes to Exhibit B to the Plan (the allocation of Common Members to DREAs) are not required to be filed with, and approved by, the Commission before they become effective.

[19] *See* Securities Exchange Act Release No. 76311 (October 29, 2015), 80 FR 68377 (November 4, 2015).

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[20]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19582 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–78547; File No. SR–MIAX–2016–24]

Self-Regulatory Organizations; Miami International Securities Exchange LLC; Notice of Filing and Immediate Effectiveness of a Proposed Rule Change To Amend Exchange Rule 517

August 11, 2016.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act")[1] and Rule 19b–4 thereunder,[2] notice is hereby given that on August 4, 2016, Miami International Securities Exchange LLC ("MIAX" or "Exchange") filed with the Securities and Exchange Commission ("Commission") a proposed rule change as described in Items I, II, and III below, which Items have been prepared by the Exchange. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Exchange is filing a proposal to amend Exchange Rule 517, Quote Types Defined, to adopt new Interpretations and Policies .01 and to make a non-substantive technical correction to the Rule. The text of the proposed rule change is available on the Exchange's Web site at *http://www.miaxoptions.com/filter/wotitle/rule_filing,* at MIAX's principal office, and at the Commission's Public Reference Room.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the Exchange included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The Exchange has prepared summaries, set forth in sections A, B, and C below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

1. Purpose

The Exchange proposes to amend Exchange Rule 517, Quote Types Defined, to adopt new Interpretations and Policies .01 to clarify that to be considered a priority quote (as described below), a quote for a long-term option contract[3] must meet the priority quote requirements established in Rule 517(b). The Exchange also proposes to make a non-substantive technical correction to section 517(b)(1)(ii) to correct a typographical error in the Rule.

For trade allocation purposes, quotes will be considered either priority quotes and trade allocation will be in accordance with Rule 514(e)(1),[4] or non-priority quotes and trade allocation will be in accordance with Rule 514(e)(2),[5] based upon a Market Maker's quote width at certain times.[6]

MIAX Rule 517(b), Quote Priority, describes the requirements for quotes on the Exchange to be considered priority quotes for allocation purposes. Specifically, MIAX Rule 517(b)(1)(i) establishes the standards which must be met to establish a quote as a priority quote at the time of execution. First, the bid/ask differential of a Market Maker's two-sided quote pair must be valid width (no wider than the bid/ask differentials outlined in Rule 603(b)(4)).[7] Second, the initial size of both the Market Maker's bid and the offer must be in compliance with the requirements of Rule 604(b)(2).[8] Third, the bid/ask differential of a Market Maker's two-sided quote pair must meet the priority quote width requirements as defined by rule[9] for each option. Fourth, at the time a locking or crossing quote or order enters the System,[10] the Market Maker's two-sided quote pair must be valid width for that option and must have been resting on the Book or,[11] immediately prior to the time the Market Maker enters a new quote that locks or crosses the MBBO,[12] the Market Maker must have had a valid width quote already existing (*i.e.,* exclusive of the Market Maker's new marketable quote or update) among his two-sided quotes for that option.[13]

The Exchange notes that strike price interval, bid/ask differential and continuous quoting requirements do not apply to long-term options series until the time to expiration is less than nine (9) months.[14] Notwithstanding these exceptions, any quote (including a quote in a long term option) must comply with Rule 517(b) to be considered a priority quote. Accordingly, the Exchange proposes to adopt Interpretations and Policies .01 to Rule 517 which will expressly state that a quote on a long-term option contract must satisfy the requirements outlined in Rule 517(b) to be considered a priority quote on the Exchange. The Exchange believes that adding proposed Interpretations and Policies .01 will clarify the requirements for establishing priority quotes for long-term option contracts on the Exchange. Further, the Exchange believes that providing additional information on how priority quotes are established for options with a time to expiration greater than nine (9) months will provide additional clarity of Exchange rules regarding priority quotes and allocations.

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[20] 17 CFR 200.30–3(a)(34).

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] The Exchange may list long-term option contracts that expire from twelve (12) to thirty-nine (39) months from the time they are listed. *See* Exchange Rule 406.

[4] After all Priority Customer Orders (if any) at the NBBO have been filled, executions at that price will be first allocated to other remaining Market Maker priority quotes, which have not received a participation entitlement, and have precedence over Professional Interest. *See* Exchange Rule 514(e)(1).

[5] If after all Market Maker priority quotes have been filled in accordance with Rule 514(e)(1) and there remains interest at the NBBO, executions will be allocated to all Professional Interest at that price. Professional Interest is defined in Rule 100 and includes among other interest, Market Maker non-priority quotes (as described in Rule 517(b)(1)(iii)) and Market Maker orders in both assigned and non-assigned classes. *See* Exchange Rule 514(e)(2).

[6] *See* Exchange Rule 517(b)(1).

[7] A Market Maker is expected to price option contracts fairly by, among other things, bidding and offering so as to create differences of no more than $5 between the bid and offer ("bid/ask differentials") following the opening rotation in an equity option contract. *See* Exchange Rule 603(b)(4).

[8] The initial size of a Market Maker incoming Standard Quote, Day eQuote and all other types of eQuotes must be for the minimum number of contracts, which minimum number shall be at least one (1) contract. The minimum number of contracts will be determined by the Exchange on a class-by-class basis and announced to the Members through a Regulatory Circular. *See* Exchange Rule 604(b)(2).

[9] The priority quote width standard established by the Exchange can have bid/ask differentials as narrow as one MPV, as wide but never wider than the bid/ask differentials outlined in Rule 603(b)(4), or somewhere in between. *See* Exchange Rule 517(b)(1)(ii).

[10] The term "System" means the automated trading system used by the Exchange for the trading of securities. *See* Exchange Rule 100.

[11] *See* Exchange Rule 517(b)(1)(i)(D)(1).

[12] The term "MBBO" means the bid or offer on the Exchange. *See* Exchange Rule 100.

[13] *See* Exchange Rule 517(b)(1)(i)(D)(2).

[14] *See* Exchange Rule 406.

The Exchange is also proposing to make a technical amendment to current Exchange Rule 517(b)(ii) by deleting the repetitive words "than the" from the Rule, which are stated twice consecutively.

2. Statutory Basis

MIAX believes that its proposed rule change is consistent with section 6(b) of the Act[15] in general, and furthers the objectives of section 6(b)(5) of the Act[16] in particular, in that it is designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, to foster cooperation and coordination with persons engaged in facilitating transactions in securities, to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest.

The proposed rule change is designed to promote just and equitable principles of trade by clarifying the operation of Exchange rules to ensure that Market Makers have complete information as to how priority quotes are established on the Exchange. Further, the proposed rule change is designed to remove impediments to and perfect the mechanisms of a free and open market and a national market system and, in general, to protect investors and the public interest, by providing enhanced guidance to Market Makers on establishing priority quotes on options with a time to expiration greater than nine (9) months. The Exchange believes that the priority quote status afforded to Market Makers quoting in long-term options should result in more liquidity and tighter spreads in these options. Clarity in the Exchange's rules regarding the establishment of priority quote status in long-term options benefits and protects the public interest by explicitly stating that Market Makers submitting quotes in long-term options can establish priority quote status by submitting such quotes with the required bid/ask differential. This should encourage more Market Makers to submit quotes on long-term options to the Exchange, and should thus result in better prices and increased liquidity in long-term options.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition that is not necessary or appropriate in furtherance of the purposes of the Act. Specifically, the Exchange believes the proposed changes will not impose any burden on intra-market competition because it applies to all MIAX participants equally. In addition, the Exchange does not believe the proposal will impose any burden on inter-market competition as the proposal is intended to clarify the operation of existing Exchange rules.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

Written comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the foregoing proposed rule change does not: (i) Significantly affect the protection of investors or the public interest; (ii) impose any significant burden on competition; and (iii) become operative for 30 days after the date of the filing, or such shorter time as the Commission may designate, it has become effective pursuant to 19(b)(3)(A) of the Act[17] and Rule 19b–4(f)(6)[18] thereunder.

At any time within 60 days of the filing of the proposed rule change, the Commission summarily may temporarily suspend such rule change if it appears to the Commission that such action is necessary or appropriate in the public interest, for the protection of investors, or otherwise in furtherance of the purposes of the Act. If the Commission takes such action, the Commission shall institute proceedings to determine whether the proposed rule should be approved or disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit written data, views, and arguments concerning the foregoing, including whether the proposed rule change is consistent with the Act. Comments may be submitted by any of the following methods:

Electronic Comments

- Use the Commission's Internet comment form (*http://www.sec.gov/rules/sro.shtml*); or
- Send an email to *rule-comments@sec.gov*. Please include File No. SR–MIAX–2016–24 on the subject line.

Paper Comments

- Send paper comments in triplicate to Secretary, Securities and Exchange Commission, 100 F Street NE., Washington, DC 20549–1090.

All submissions should refer to File Number SR–MIAX–2016–24. This file number should be included on the subject line if email is used. To help the Commission process and review your comments more efficiently, please use only one method. The Commission will post all comments on the Commission's Internet Web site (*http://www.sec.gov/rules/sro.shtml*). Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for Web site viewing and printing in the Commission's Public Reference Room, 100 F Street NE., Washington, DC 20549, on official business days between the hours of 10:00 a.m. and 3:00 p.m. Copies of the filing also will be available for inspection and copying at the principal office of the Exchange. All comments received will be posted without change; the Commission does not edit personal identifying information from submissions. You should submit only information that you wish to make available publicly. All submissions should refer to File Number SR–MIAX–2016–24 and should be submitted on or before September 7, 2016.

For the Commission, by the Division of Trading and Markets, pursuant to delegated authority.[19]

Robert W. Errett,

Deputy Secretary.

[FR Doc. 2016–19578 Filed 8–16–16; 8:45 am]

BILLING CODE 8011–01–P

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[15] 15 U.S.C. 78f(b).

[16] 15 U.S.C. 78f(b)(5).

[17] 15 U.S.C. 78s(b)(3)(A).

[18] 17 CFR 240.19b–4(f)(6). In addition, Rule 19b–4(f)(6) requires a self-regulatory organization to give the Commission written notice of its intent to file the proposed rule change at least five business days prior to the date of filing of the proposed rule change, or such shorter time as designated by the Commission. The Exchange has satisfied this requirement.

[19] 17 CFR 200.30–3(a)(12).

DEPARTMENT OF STATE

[Public Notice: 9671]

30-Day Notice of Proposed Information Collection: Shrimp Exporter's/Importer's Declaration

ACTION: Notice of request for public comment and submission to OMB of proposed collection of information.

SUMMARY: The Department of State has submitted the information collection described below to the Office of Management and Budget (OMB) for approval. In accordance with the Paperwork Reduction Act of 1995 we are requesting comments on this collection from all interested individuals and organizations. The purpose of this Notice is to allow 30 days for public comment.

DATES: Submit comments directly to the Office of Management and Budget (OMB) up to September 16, 2016.

ADDRESSES: Direct comments to the Department of State Desk Officer in the Office of Information and Regulatory Affairs at the Office of Management and Budget (OMB). You may submit comments by the following methods:

- *Email: oira_submission@omb.eop.gov.* You must include the DS form number, information collection title, and the OMB control number in the subject line of your message.
- *Fax:* 202–395–5806. Attention: Desk Officer for Department of State.

FOR FURTHER INFORMATION CONTACT: Direct requests for additional information regarding the collection listed in this notice, including requests for copies of the proposed collection instrument and supporting documents, to Section 609 Program Manager, Office of Marine Conservation, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State, Washington, DC 20520–2758, who may be reached on 202–647–3263 or at *DS2031@state.gov.*

SUPPLEMENTARY INFORMATION:

- *Title of Information Collection:* Shrimp Exporter's/Importer's Declaration.
- *OMB Control Number:* 1405–0095.
- *Type of Request:* Extension of a Currently Approved Collection.
- *Originating Office:* Bureau of Oceans and International Environmental and Scientific Affairs, Office of Marine Conservation (OES/OMC).
- *Form Number:* DS–2031.
- *Respondents:* Business or other for-profit organizations.
- *Estimated Number of Respondents:* 3,000.
- *Estimated Number of Responses:* 10,000.
- *Average Time per Response:* 10 minutes.
- *Total Estimated Burden Time:* 1,666 hours.
- *Frequency:* On occasion.
- *Obligation to Respond:* Mandatory.

We are soliciting public comments to permit the Department to:

- Evaluate whether the proposed information collection is necessary for the proper functions of the Department.
- Evaluate the accuracy of our estimate of the time and cost burden for this proposed collection, including the validity of the methodology and assumptions used.
- Enhance the quality, utility, and clarity of the information to be collected.
- Minimize the reporting burden on those who are to respond, including the use of automated collection techniques or other forms of information technology.

Please note that comments submitted in response to this Notice are public record. Before including any detailed personal information, you should be aware that your comments as submitted, including your personal information, will be available for public review.

Abstract of proposed collection: The DS–2031 form is necessary to document imports of shrimp and shrimp products pursuant to the State Department's implementation of Section 609 of Public Law 101–162, which prohibits the entry into the United States of shrimp harvested in ways which are harmful to sea turtles. Respondents are shrimp or shrimp product exporters and government officials in countries that export shrimp or shrimp product to the United States. The importer is required to present the DS–2031 form at the port of entry into the United States, to retain the DS–2031 form for a period of three years subsequent to entry, and during that time to make the DS–2031 form available to U.S. Customs and Border Protection or the Department of State upon request.

Methodology: The DS–2031 form is completed by the exporter, the importer, and under certain conditions a government official of the harvesting country. The DS–2031 form accompanies shipments of shrimp and shrimp products to the United States and is to be made available to U.S. Customs and Border Protection at the time of entry and for three years after entry.

Dated: August 8, 2016.

David A. Balton,

Deputy Assistant Secretary of State for Oceans and Fisheries, Bureau of Oceans and International Environmental and Scientific Affairs, Department of State.

[FR Doc. 2016–19631 Filed 8–16–16; 8:45 am]

BILLING CODE 4710–09–P

SUSQUEHANNA RIVER BASIN COMMISSION

Commission Meeting; Correction

AGENCY: Susquehanna River Basin Commission.

ACTION: Notice; correction.

SUMMARY: The Susquehanna River Basin Commission published a document in the **Federal Register** of August 10, 2016 (81 FR 52946), concerning its regular business meeting on September 8, 2016, in Cooperstown, New York. The document was revised to update agenda item #6 and add an additional agenda item, to be addressed at the business meeting, contained below in the **SUPPLEMENTARY INFORMATION** section of this notice.

DATES: The meeting will be held on Thursday, September 8, 2016, at 9 a.m.

ADDRESSES: The meeting will be held at The Otesaga Resort Hotel, Ballroom, 60 Lake Street, Cooperstown, NY 13326.

FOR FURTHER INFORMATION CONTACT: Jason E. Oyler, General Counsel, telephone: (717) 238–0423, ext. 1312; fax: (717) 238–2436.

SUPPLEMENTARY INFORMATION: The business meeting will include actions or presentations on the following items: (1) Informational presentation of interest to the Upper Susquehanna Subbasin area; (2) proposed rescission of the Commission's Information Technology Services Fee Policy; (3) ratification/approval of contracts/grants; (4) release of proposed rulemaking for public comment; (5) notice for Montage Mountain Resorts, LP project sponsor to appear and show cause before the Commission; and (6) Regulatory Program projects, including requests to extend emergency certificates for Furman Foods, Inc. and Standing Stone Golf Club. The business meeting may also include action on regulatory compliance matters for Panda Liberty LLC, Panda Patriot LLC, and Hummel Station LLC.

Projects and proposed rescission of the Commission's Information Technology Services Fee Policy listed for Commission action are those that were the subject of a public hearing conducted by the Commission on

August 4, 2016, and identified in the notice for such hearing, which was published in 81 FR 44407, July 7, 2016.

The public is invited to attend the Commission's business meeting. Comments on the Regulatory Program projects and proposed rescission of the Commission's Information Technology Services Fee Policy were subject to a deadline of August 15, 2016. Written comments pertaining to other items on the agenda at the business meeting may be mailed to the Susquehanna River Basin Commission, 4423 North Front Street, Harrisburg, Pennsylvania 17110–1788, or submitted electronically through *http://www.srbc.net/pubinfo/publicparticipation.htm*. Such comments are due to the Commission on or before September 2, 2016. Comments will not be accepted at the business meeting noticed herein.

Authority: Pub. L. 91–575, 84 Stat. 1509 *et seq.*, 18 CFR parts 806, 807, and 808.

Dated: August 12, 2016.

Stephanie L. Richardson,

Secretary to the Commission.

[FR Doc. 2016–19649 Filed 8–16–16; 8:45 am]

BILLING CODE 7040–01–P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Comments and Notice of Public Hearing Concerning Russia's Implementation of Its WTO Commitments

AGENCY: Office of the United States Trade Representative.

ACTION: Notice of public hearing and request for comments.

SUMMARY: The interagency Trade Policy Staff Committee (TPSC) will convene a public hearing and seek public comment to assist the Office of the United States Trade Representative (USTR) in the preparation of its annual report to Congress on Russia's implementation of its commitments as a Member of the World Trade Organization (WTO).

DATES: If you want to testify at the hearing, you must provide written notification and a summary of your testimony by Tuesday, September 20, 2016. Written comments also are due by Tuesday, September 20, 2016. The hearing will be held on Friday, September 30, 2016, beginning at 9:30 a.m. in Rooms 1 & 2, 1724 F Street NW., Washington, DC 20508.

ADDRESSES: You should submit notifications of intent to testify and written comments through the Federal eRulemaking Portal: *http://www.regulations.gov*. Follow the instructions for submitting comments in section 3 below. For alternatives to on-line submissions, please contact Yvonne Jamison, Trade Policy Staff Committee, at (202) 395–3475.

FOR FURTHER INFORMATION CONTACT: For procedural questions concerning written comments or participating in the public hearing, contact Yvonne Jamison at (202) 395–3475. Direct all other questions regarding this notice to Betsy Hafner, Deputy Assistant United States Trade Representative for Russia and Eurasia, at (202) 395–9124.

SUPPLEMENTARY INFORMATION:

1. Background

Russia became a Member of the WTO on August 22, 2012, and on December 21, 2012, following the termination of the application of the Jackson-Vanik amendment to Russia and the extension of permanent normal trade relations to the products of Russia, the United States and Russia both filed letters with the WTO withdrawing their notices of non-application and consenting to have the WTO Agreement apply between them. In accordance with section 201(a) of the Russia and Moldova Jackson-Vanik Repeal and Sergei Magnitskiy Rule of Law Accountability Act of 2012 (Pub. L. 112–208), USTR is required to submit, by December 21st of each year, a report to Congress on the extent to which Russia is implementing the WTO Agreement, including the Agreement on the Application of Sanitary and Phytosanitary Measures and the Agreement on Trade Related Aspects of Intellectual Property Rights. The Report also must assess Russia's progress on acceding to the Information Technology Agreement (ITA) and the Government Procurement Agreement (GPA). In addition, to the extent that USTR finds that Russia is not implementing fully the WTO Agreement or is not making adequate progress in acceding to the ITA or the GPA, USTR must describe in the report the actions it plans to take to encourage Russia to improve its implementation and/or increase its accession efforts. In accordance with section 201(a), and to assist it in preparing this year's report, the TPSC is hereby soliciting public comment. Last year's report is available on USTR's Web site: *https://ustr.gov/sites/default/files/2015-Report-on-Implementation-Enforcement-Russia-WTO-Commitments.pdf*

The terms of Russia's accession to the WTO are contained in the Marrakesh Agreement Establishing the World Trade Organization and the Protocol on the Accession of the Russian Federation to the WTO (including its annexes) (Protocol). The Report of the Working Party on the Accession of the Russian Federation (Working Party Report) provides detail and context to the commitments listed in the Protocol. The Protocol and Working Party Report can be found on USTR's Web page, *https://ustr.gov/node/5887* or on the WTO Web site, *http://docsonline.wto.org* (document symbols: WT/ACC/RUS/70, WT/MIN(11)/2, WT/MIN(11)/24, WT/L/839, and WT/ACC/RUS/70/Add.1, WT/ACC/RUS/70/Add.2.

2. Public Comment and Hearing

USTR invites written comments and/or oral testimony of interested persons on Russia's implementation of the commitments made in connection with its accession to the WTO, including, but not limited to, commitments in the following areas:

(a) import regulation (*e.g.*, tariffs, tariff-rate quotas, quotas, import licenses);

(b) export regulation;

(c) subsidies;

(d) standards and technical regulations;

(e) sanitary and phytosanitary measures;

(f) trade-related investment measures;

(g) taxes and charges levied on imports and exports;

(h) other internal policies affecting trade;

(i) intellectual property rights (including intellectual property rights enforcement);

(j) services;

(k) rule of law issues (*e.g.*, transparency, judicial review, uniform administration of laws and regulations);

(l) trade-related investment measures; and

(m) other WTO commitments.

You must submit written comments no later than Tuesday, September 20, 2016.

A hearing will be held on Friday, September 30, 2016, in Rooms 1 & 2, 1724 F Street NW., Washington, DC 20508. Persons wishing to testify at the hearing must provide written notification of their intention by 11:59 p.m., Tuesday, September 20, 2016. The intent to testify notification must be made in the "Type Comment" field under docket number USTR–2016–0014 on the *www.regulations.gov* Web site and should include the name, address and telephone number of the person presenting the testimony. A summary of the testimony should be attached by using the "Upload File" field. The name of the file also should include who will be presenting the testimony. Remarks at the hearing should be limited to no more than five minutes to allow for possible questions from the TPSC.

You should submit all documents in accordance with the instructions in section 3 below.

3. Requirements for Submissions

Persons submitting a notification of intent to testify and/or written comments must do so in English and must identify (on the first page of the submission) "Russia's WTO Implementation of its WTO Commitments." In order to be assured of consideration, comments should be submitted by 11:59 p.m., September 20, 2016.

In order to ensure the timely receipt and consideration of comments, USTR strongly encourages commenters to make on-line submissions, using the *www.regulations.gov* Web site. To submit comments via *www.regulations.gov,* enter docket number USTR–2016–0014 on the home page and click "search." The site will provide a search-results page listing all documents associated with this docket. Find a reference to this notice and click on the link entitled "Comment Now!" For further information on using the *www.regulations.gov* Web site, please consult the resources provided on the Web site by clicking on "How to Use Regulations.gov" on the bottom of the home page.

The *www.regulations.gov* Web site allows users to provide comments by filling in a "Type Comment" field, or by attaching a document using an "Upload File" field. USTR prefers that comments be provided in an attached document. If a document is attached, it is sufficient to type "See attached" in the "Type Comment" field. USTR prefers submissions in Microsoft Word (.doc) or Adobe Acrobat (.pdf). If the submission is in an application other than those two, please indicate the name of the application in the "Type Comment" field.

For any comments submitted electronically containing business confidential information, the file name of the business confidential version should begin with the characters "BC". Any page containing business confidential information must be clearly marked "BUSINESS CONFIDENTIAL" on the top of that page. Filers of submissions containing business confidential information also must submit a public version of their comments. The file name of the public version should begin with the character "P". The "BC" and "P" should be followed by the name of the person or entity submitting the comments or reply comments. Filers submitting comments containing no business confidential information should name their file using the name of the person or entity submitting the comments.

Please do not attach separate cover letters to electronic submissions; rather, include any information that might appear in a cover letter in the comments themselves. Similarly, to the extent possible, please include any exhibits, annexes, or other attachments in the same file as the submission itself, not as separate files.

As noted, USTR strongly urges submitters to file comments through *www.regulations.gov.* Any alternative arrangements must be made with Yvonne Jamison in advance of transmitting a comment. You can contact Ms. Jamison at (202) 395–3475. General information concerning USTR is available at *www.ustr.gov.*

Comments will be placed in the docket and open to public inspection, except business confidential information. Comments may be viewed on the *www.regulations.gov* Web site by entering the relevant docket number in the search field on the home page.

Edward Gresser,

Chair of the Trade Policy Staff Committee, Office of the United States Trade Representative.

[FR Doc. 2016–19593 Filed 8–16–16; 8:45 am]

BILLING CODE 3290–F6–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

Ninety-Sixth Meeting Special Committee 159 Global Positioning System

AGENCY: Federal Aviation Administration (FAA), U.S. Department of Transportation (DOT).

ACTION: NINETY-SIXTH MEETING Special Committee 159 Global Positioning System.

SUMMARY: The FAA is issuing this notice to advise the public of a meeting of NINETY-SIXTH MEETING Special Committee 159 Global Positioning System.

DATES: The meeting will be held October 14–21, 2016, 09:00 a.m.–5:00 p.m. (unless stated otherwise)

ADDRESSES: The meeting will be held at: RTCA Conference Rooms, 1150 18th NW., Suite 910, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Rebecca Morrison at *rmorrison@rtca.org* or (202) 330–0654, or The RTCA Secretariat, 1150 18th Street NW., Suite 910, Washington, DC 20036, or by telephone at (202) 833–9339, fax at (202) 833–9434, or Web site at *http://www.rtca.org.*

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463, 5 U.S.C., App.), notice is hereby given for a meeting of the NINETY-SIXTH MEETING Special Committee 159 Global Positioning System. The agenda will include the following:

Specific Working Group Sessions

Friday October 14, 2016

- Morning Teleconference—10:00 a.m.—Working group 2A, GPS/GLONASS, Webex. Contact Rebecca Morrison for details

Monday October 17, 2016

- All Day–9:00 a.m.–5:00 p.m., Working Group 2, GPS/WAAS, 9th Floor NBAA/Colson Room

Tuesday October 18, 2016

- All Day—9:00 a.m.–5:00 p.m., Working Group 2C, GPS/Inertial, 9th Floor A4A/ARINC Room
- All Day—9:00 a.m.–5:00 p.m., Working Group 4, GPS/Precision Landing, 9th Floor NBAA/Colson
- Half Day—9:00 a.m.–12:00 p.m., Working Group 2, GPS/WAAS, 9th Floor NBAA/Colson Room
- Half Day—1:00 p.m.–5:00 p.m., Working Group 2A, GPS/GLONASS, 4th Floor Small Board Room

Wednesday October 19, 2016

- All Day 9:00 a.m.–5:00 p.m., Working Group 2A, GPS/GLONASS, 4th Floor Small Board Room
- All Day—9:00 a.m.–5:00 p.m., Working Group 2C, GPS/Inertial, 9th Floor ARINC/A4A Room
- All Day—9:00 a.m.–5:00 p.m., Working Group 4, GPS/Precision Landing, 9th Floor NBAA/Colson Room

Thursday October 20, 2016

- Morning—9:00 a.m.–12:00 p.m., Working Group 2C, GPS/Inertial, 9th Floor ARINC/A4A Room
- All Day—9:00 a.m.–5:00 p.m., Working Group 4, GPS/Precision Landing, 9th Floor NBAA/Colson
- Morning—9:00 a.m.–12:00 p.m., Working Group 7, GPS/Antennas, 4th Floor Large Board Room
- Afternoon—1:00 p.m.–5:00 p.m., Working Group 6, GPS/Interference, 4th Floor Large Board Room

Friday October 21, 2016

- PLENARY SESSION—SEE AGENDA BELOW—starting at 9:00 a.m. 9th Floor NBAA

1. Introductory Remarks: DFO, RTCA and Chairman.

2. Approval of Summary of the Ninety-Fifth Meeting held March, 2016, RTCA Paper No. 189–16/SC159–1050.

3. Final Review and Comment (FRAC) activities.

a. DO–229E Update
b. GPS/GLONASS MOPS

4. Review Working Group (WG) Progress and Identify Issues for Resolution.

a. GPS/WAAS (WG–2)
b. GPS/GLONASS (WG–2A)
c. GPS/Inertial (WG–2C)
d. GPS/Precision Landing Guidance (WG–4)
e. GPS/Interference (WG–6)
f. GPS/Antennas (WG–7)

5. Review of EUROCAE Activities.
6. Action Item Review.

a. DME Interference to GNSS signals in the future
b. Draft formal communication to SBAS providers and other standards bodies informing them of SC–159 work products and efforts

7. Assignment/Review of Future Work.
8. Other Business.
9. Date and Place of Next Meeting.
10. Adjourn.

Attendance is open to the interested public but limited to space availability. With the approval of the chairman, members of the public may present oral statements at the meeting. Persons wishing to present statements or obtain information should contact the person listed in the **FOR FURTHER INFORMATION CONTACT** section. Members of the public may present a written statement to the committee at any time.

Issued in Washington, DC, on August 12, 2016.

Mohannad Dawoud,

Management & Program Analyst, Partnership Contracts Branch, ANG–A17 NextGen, Procurement Services Division, Federal Aviation Administration.

[FR Doc. 2016–19604 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2015–0019]

Petition for Waiver of Compliance

In accordance with part 211 of Title 49 Code of Federal Regulations (CFR), this provides the public notice that by a document dated May 23, 2016, Norfolk Southern Corporation (NS) requested that the Federal Railroad Administration's (FRA) Railroad Safety Board (Board) amend NS' existing waiver to allow an expansion of the territory for its nonstop continuous rail testing process in Docket Number FRA–2015–0019. The projected start date to implement testing on the additional territory would be July 1, 2016, and would continue for a period up to July 1, 2018. The original waiver, granted by FRA's decision letter dated July 8, 2015, allowed NS to perform the continuous nonstop rail testing process on various main track segments in the Dearborn, Lake, Pittsburgh, and Harrisburg Divisions.

In a decision letter dated March 21, 2016, FRA granted NS' request to expand its continuous nonstop rail testing program to additional trackage in the Central Georgia, Dearborn, and Lake Divisions.

In the current request, NS seeks permission to expand the continuous nonstop testing to additional territory under the existing waiver conditions. Specifically, the additional territory is:

Alabama Division: Memphis District (Chattanooga, TN, to Memphis, TN, MP 279.83 A–551.7 A, Tracks 1 and 2); AGS District (Chattanooga, TN, to Meridian, MS, MP 0.0–295.44, Tracks 1 and 2); NO&NE District (Meridian, MS, to New Orleans, LA, MP NO 0.35–195.92, Tracks 1 and 2); East End District (Atlanta, GA, to Birmingham, AL, MP 650.00–798.36, Tracks 1 and 2). Central Division: Knoxville District (Bristol, TN, to Ooltewah, TN, MP 0.00 A–235.07 A, Tracks 1 and 2); Knoxville District (Knoxville, TN, to Harriman, TN, MP 0.00 CO–51.3 D, Tracks 1 and 2); Louisville District (Louisville, KY, to Danville, KY, MP 268.3 W–357.65 W, Tracks 1 and 2). Dearborn Division: Detroit Line (Gibralter, OH, to Lasalle, OH, MP HK 20.00–HK 40.00); Detroit Line (Blaha, MI, to Swan Creek, OH, MP DR 20.00–DR 57.70, Tracks 1 and 2). Georgia Division: Atlanta South District (Atlanta, GA to Macon, GA, MP 158.80 H to MP 240.40 H, Tracks 1 and 2); Macon/Valdosta District (Macon, GA, to Jacksonville, FL, MP 0.00 G to MP 260.56 G, Tracks 1 and 2). Harrisburg Division: Reading/Harrisburg Line (Belt, PA, to Titus, PA, MP AF 5.60 to AF 13.00, Tracks 1 and 2); Lehigh Line (Bethlehem, PA, to Lehighton, PA, MP LB 84.00 to LB 114.70); Lehigh Line (Manville, PA, to Bethlehem, PA, MP LE 35.80 to LE 88.90, Tracks 1 and 2); Lurgan Branch (Capital, PA, to Town, PA, MP LG 0.00 to HW 73.70, Tracks 1 and 2); Reading Line (Blandon, PA, to Allentown, PA, MP RV 7.50 to RV 36.30, Tracks 1 and 2); Reading Line (Blandon, PA, to Belt, PA, MP TK 0.00 to TK 5.40, Tracks 1 and 2); Reading Line (Tulp, PA, to Wyomissing, PA, MP TW 8.40 to TW 9.40). Illinois Division: Lafayette District (Peru, IN, to Decatur, IL, MP D 204.53 to D 375.59, Tracks 1 and 2); Brooklyn District (Decatur, IL, to East St. Louis, IL, MP D 375.59 to D 485.00, Tracks 1 and 2); Springfield/Hannibal District (Decatur, IL, to Moberly, MO, MP DH 376.50 to MP H 69.85); St. Louis/Kansas City District (St. Louis, MO, to Kansas City, MO, MP S 3.00 to S 274.83, Tracks 1 and 2); Southern East/West District (East St. Louis, IL, to New Albany, IN, MP 3.28 W to 268.30 W). Lake Division: Dayton District (Columbus, OH, to Sharonville, OH, MP CJ 134.40 to CJ 255.10, Tracks 1 and 2); Huntington District (Butler, IN, to Peru, IN, MP D 114.10 to D 204.53, Tracks 1 and 2); Marion District (Goshen, IN, to Anderson, IN, MP 0.00 to MP 110.98); Kenova/Columbus District (Williamson, WV, to Columbus, OH, MP N 470.00 to N 704.50, Tracks 1 and 2); Sandusky District (Columbus, OH, to Flat Rock, OH, MP S 1.00 to S 96.00, Tracks 1 and 2); Frankfort District (Muncie, IN, to Lafayette, IN, MP SP 173.70 to SP 259.00). Piedmont Division: Washington District (Manassas, VA, to Front Royal, VA, MP B 0.00 to B 51.00); Washington/Danville/Charlotte/Greenville District (Alexandria, VA, to Atlanta, GA, MP 9.25 to 635.21, Tracks 1 and 2). Pittsburgh Division: Cleveland Line (Rochester, OH, to Alliance, OH, MP RD 0.00 to RD 67.00, Tracks 1 and 2). Pocahontas Division: Hagerstown/Roanoke District (Hagerstown, MD, to Roanoke, VA, MP H 0.63 to H 239.28, Tracks 1 and 2); Norfolk/Blue Ridge/Christiansburg/Pocahontas District (Norfolk, VA, to Williamson, WV, MP N 1.23 to N 470.00, Tracks 1 and 2); Pulaski District (Walton, VA, to Bristol, VA, MP NB 297.63 to NB 408.38, Tracks 1 and 2); Altavista/Whitethorne District (Abilene, VA, to Roanoke, VA, MP V 141.39 to V 316.86).

A copy of the petition, as well as any written communications concerning the petition, is available for review online at *www.regulations.gov* and in person at the U.S. Department of Transportation's (DOT) Docket Operations Facility, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590. The Docket Operations Facility is open from 9 a.m. to 5 p.m., Monday through Friday, except Federal Holidays.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (*e.g.,* Waiver Petition Docket Number FRA–2015–0019) and may be submitted by any of the following methods:

- Web site: *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- Fax: 202–493–2251.
- Mail: Docket Operations Facility, U.S. Department of Transportation, 1200 New Jersey Avenue SE., W12–140, Washington, DC 20590.
- Hand Delivery: 1200 New Jersey Avenue SE., Room W12–140, Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

Communications received by October 3, 2016 will be considered by FRA before final action is taken. Comments received after that date will be considered as far as practicable.

Anyone is able to search the electronic form of any written communications and comments received into any of our dockets by the name of the individual submitting the comment (or signing the document, if submitted on behalf of an association, business, labor union, etc.). In accordance with 5 U.S.C. 553(c), DOT solicits comments from the public to better inform its processes. DOT posts these comments, without edit, including any personal information the commenter provides, to *www.regulations.gov,* as described in the system of records notice (DOT/ALL–14 FDMS), which can be reviewed at *www.dot.gov/privacy.* See also *http://www.regulations.gov/#!privacyNotice for the privacy notice of regulations.gov.*

Issued in Washington, DC, on August 12, 2016.

Karl Alexy,

Director, Office of Safety Analysis.

[FR Doc. 2016–19654 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

Federal Railroad Administration

[Docket Number FRA–2016–0002–N–18]

Proposed Agency Information Collection Activities; Comment Request

AGENCY: Federal Railroad Administration (FRA), U.S. Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: Under the Paperwork Reduction Act of 1995 (PRA), this notice announces that FRA is forwarding the renewal of the information collection requirements (ICRs) abstracted below to the Office of Management and Budget (OMB) for review and comment. The ICRs describe the nature of the information collections and expected burdens. The **Federal Register** notice with a 60-day comment period soliciting comments on the ICRs was published on May 3, 2016.

DATES: Comments must be submitted on or before September 16, 2016.

FOR FURTHER INFORMATION CONTACT: Mr. Robert Brogan, Information Collection Clearance Officer, Office of Railroad Safety, Safety Regulatory Analysis Division, RRS–21, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 25, Washington, DC 20590, (202) 493–6292, or Ms. Kimberly Toone, Information Collection Clearance Officer, Office of Administration, Office of Information Technology, RAD–20, Federal Railroad Administration, 1200 New Jersey Avenue SE., Mail Stop 35, Washington, DC 20590, (202) 493–6132. These telephone numbers are not toll-free.

SUPPLEMENTARY INFORMATION: The PRA, 44 U.S.C. 3501–3520 (1995), and its implementing regulations, 5 CFR part 1320, require Federal agencies to issue two notices seeking public comment on information collection activities before OMB may approve paperwork packages. *See* 44 U.S.C. 3506, 3507; 5 CFR 1320.5, 1320.8(d)(1), and 1320.12. On May 3, 2016, FRA published a 60-day notice in the **Federal Register** soliciting comment on ICRs for which FRA is seeking OMB approval. *See* 81 FR 26619. FRA received no comments in response to that notice.

Before OMB decides whether to approve these proposed ICRs, it must provide 30 days for public comment. *See* 44 U.S.C. 3507(b), 5 CFR 1320.12(d). Federal law requires OMB to approve or disapprove paperwork packages between 30 and 60 days after the 30-day notice is published. *See* 44 U.S.C. 3507 (b)–(c); 5 CFR 1320.12(d); *see also* 60 FR 44978, 44983, Aug. 29, 1995. OMB believes the 30-day notice informs the regulated community to file relevant comments and affords the agency adequate time to digest public comments before it renders a decision. *See* 60 FR 44983, Aug. 29, 1995. Therefore, respondents should submit their respective comments to OMB within 30 days of publication to best ensure their full consideration. *See* 5 CFR 1320.12(c); *see also* 60 FR 44983, Aug. 29, 1995.

The summary below describes the nature of the ICRs and expected burdens. FRA is submitting the renewal request for OMB clearance the PRA requires.

Title: Filing of Dedicated Cars.

OMB Control Number: 2130–0502.

Abstract: Title 49 CFR part 215 contains standards for freight car safety and prescribes certain conditions railroads must follow to move freight cars in dedicated service. Dedicated service means the exclusive assignment of railroad cars to the transportation of freight between specified points under the conditions defined in § 215.5(d), including stenciling, or otherwise displaying, in clear legible letters on each side of the car body the words "Dedicated Service." A railroad must identify those cars in a written report to FRA before the railroad assigns the cars to dedicated service. The railroad must file that report with FRA not less than 30 days before the cars operate in dedicated service. FRA uses the information collected under § 215.5(d) to determine the number of railroads affected, the number and type of cars involved, the commodities being carried, and the territorial and speed limits within which the cars will be operated. FRA reviews these reports to determine if the equipment is safe to operate and if the operation qualifies for dedicated service. The information collected indicates to FRA and State inspectors the particular or "dedicated" cars are in special service and that certain restrictions apply to their movement under part 215. FRA inspectors may cite cars not in compliance for violations. Railroads also use the information collected to provide identification and control so dedicated cars remain in the prescribed service.

Type of Request: Extension without change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): N/A.

Total Annual Estimated Burden: 4 hours.

Total Annual Estimated Responses: 4.

Title: Special Notice for Repairs.

OMB Control Number: 2130–0504.

Abstract: Under 49 CFR part 216, FRA and State inspectors may issue a Special Notice for Repairs to notify railroads in writing of an unsafe condition involving a locomotive, car, or track. The railroad must notify FRA in writing when the equipment is returned to service or the track restored to a condition permitting operations at speeds authorized for a higher class, specifying the repairs completed. FRA and State inspectors use this information to remove from service freight cars, passenger cars, and locomotives until they can be restored to a serviceable condition. They also use this information to reduce the maximum authorized speed on a section of track until repairs can be made.

Type of Request: Extension without change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): Form FRA F 6180.8; Form FRA F6180.8a.

Total Annual Estimated Burden: 20 hours.

Total Annual Estimated Responses: 72.

Title: Rear-End Marking Devices.

OMB Control Number: 2130–0523.

Abstract: FRA regulations in 49 CFR part 221 contain requirements for rear end marking devices and for railroads to give FRA a detailed description of the type of marking devices used for any locomotive operating singly or for cars or locomotives operating at the end of a train (trailing end) to ensure they meet minimum standards for visibility and display. Specifically, part 221 requires railroads to furnish a certification it has tested each device consistent with current "Guidelines for Testing of Rear End Marking Devices." Additionally, part 221 requires railroads to furnish detailed test records, which include the testing organizations, description of tests, number of samples tested, and the test results, to demonstrate compliance with the performance standard.

Request: Extension without change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): N/A.

Total Annual Estimated Burden: 39 hours.

Total Annual Estimated Responses: 4.

Title: Locomotive Certification (Noise Compliance Regulations).

OMB Control Number: 2130–0527.

Abstract: FRA's noise enforcement procedures in 49 CFR part 210, encompass rail yard noise source standards the Environmental Protection Agency (EPA) publishes. EPA has authority to set these standards under the Noise Control Act of 1972. Information FRA collects under part 210 is necessary to ensure compliance with EPA noise standards for new locomotives.

Request: Extension without change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): Form FRA F 6180.49A.

Total Annual Estimated Burden: 2,767 hours.

Total Annual Estimated Responses: 1,582.

Title: Railroad Police Officers.

OMB Control Number: 2130–0537.

Abstract: FRA regulations in 49 CFR part 207 require railroads to notify states of all designated police officers who perform duties outside of their respective jurisdictions. This is necessary to verify proper police authority.

Request: Extension without change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): N/A.

Total Annual Estimated Burden: 181 hours.

Total Annual Estimated Responses: 70.

Title: Foreign Railroads Foreign-Based (FRFB) Employees Who Perform Train or Dispatching Service in the United States.

OMB Control Number: 2130–0555.

Abstract: For foreign-based railroads with an FRA-approved foreign workplace alcohol and drug testing program equivalent to 49 CFR part 219, subparts B, E, F, and G, this FRA regulation requires removal from service of FRFB train and dispatching service employees who test positive for unauthorized use of alcohol and drugs. Part 219 testing enhances safety and serves as a deterrent to other FRFB train and dispatching service employees who might be tempted to use unauthorized drugs or alcohol. FRA uses this collection of information to determine the compliance of FRFB train and dispatching service employees and their employers with the prohibitions against the abuse of alcohol and controlled substances spelled out in part 219.

Request: Extension with change of a currently approved information collection.

Affected Public: Businesses (Railroads).

Form(s): N/A.

Total Annual Estimated Burden: 27 hours.

Total Annual Estimated Responses: 91.

Addresses: Send comments regarding these information collections to the Office of Information and Regulatory Affairs, Office of Management and Budget, 725 Seventeenth Street NW., Washington, DC 20503, Attention: FRA Desk Officer. Comments may also be sent via email to OMB at the following address: *oira_submissions@omb.eop.gov.*

Comments are invited on the following: Whether the proposed collections of information are necessary for the proper performance of the functions of the Department, including: (1) Whether the information will have practical utility; the accuracy of the Department's estimates of the burden of the proposed information collections; (2) ways to enhance the quality, utility, and clarity of the information to be collected; and (3) ways to minimize the burden of the collections of information on respondents, including the use of automated collection techniques or other forms of information technology.

A comment to OMB is best assured of having its full effect if OMB receives it within 30 days of publication of this notice in the **Federal Register**.

Authority: 44 U.S.C. 3501–3520.

Issued in Washington, DC, on August 12, 2016.

Sarah L. Inderbitzin,

Acting Chief Counsel.

[FR Doc. 2016–19626 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–06–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

[Docket No. DOT–NHTSA–2016–0082]

Notice and Request for Comments

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Notice and request for comments.

SUMMARY: The Department of Transportation (DOT) invites public comments about our intention to request the Office of Management and Budget (OMB) approval to renew an information collection. Before a Federal agency can collect certain information from the public, it must receive approval from the Office of Management and Budget (OMB). Under procedures established by the Paperwork Reduction Act of 1995, before seeking OMB approval, Federal agencies must solicit public comment on proposed collections of information, including extensions and reinstatement of previously approved collections.

DATES: Written comments should be submitted by October 17, 2016.

ADDRESSES: You may submit comments [identified by DOT Docket No. NHTSA–XX–XX] by any of the following methods:

- *Federal eRulemaking Portal:* Go to *http://www.regulations.gov.* Follow the online instructions for submitting comments.
- *Mail: Docket Management Facility:* U.S. Department of Transportation, 1200 New Jersey Avenue SE., West Building Ground Floor, Room W12–140, Washington, DC 20590–0001.
- *Hand Delivery or Courier:* West Building Ground Floor, Room W12–140, 1200 New Jersey Avenue SE., between 9 a.m. and 5 p.m. ET, Monday through Friday, except Federal holidays. Telephone: 1–800–647–5527.
- *Fax:* 202–493–2251.

FOR FURTHER INFORMATION CONTACT: Shirlene Ball, 202–366–2245, Office of the Chief Information Officer, NPO–420, U.S. Department of Transportation, 1200 New Jersey Avenue SE., Washington, DC 20590.

SUPPLEMENTARY INFORMATION:

OMB Control Number: 2127–0588.

Title: Air Bag Deactivation.

Type of Review: Renewal of a previously approved information collection.

Abstract: If a private individual or lessee wants to install an air bag on-off switch to turn-off either or both frontal air bags, they must complete Form OMB 2127–0588 to certify certain statements regarding use of the switch. The dealer or business must, in turn, submit the completed forms to NHTSA within seven days. The submission of the completed forms by the dealers and repair business to NHTSA, as required, will serve the agency several purposes. They will aid the agency in monitoring the number of authorization requests submitted and the pattern in claims of risk group membership. The completed forms will enable the agency to determine whether the dealers and repair business are complying with the terms of the exemption, which include a requirement that the dealers and repair businesses accept only fully completed forms. Finally, submission of the completed forms to the agency will promote honesty and accuracy in the filling out of the forms by vehicle owners. The air bag on-off switches are installed only in vehicles in which the risk of harm needs to be minimized on a case-by-case basis.

Affected Public: Private Individuals, fleet owners and lessees, motor vehicle dealers, and repair business.

Estimated Number of Respondents: 750.

Number of Responses: 750.

Estimated Total Annual Burden: 375.

Public Comments Invited: You are asked to comment on any aspect of this information collection, including (a) Whether the proposed collection of information is necessary for the Department's performance; (b) the accuracy of the estimated burden; (c) ways for the Department to enhance the quality, utility and clarity of the information collection; and (d) ways that the burden could be minimized without reducing the quality of the collected information. The agency will summarize and/or include your comments in the request for OMB's clearance of this information collection.

Authority: The Paperwork Reduction Act of 1995; 44 U.S.C. Chapter 35, as amended; and 49 CFR 1:48.

Kevin Mahoney,

Director, Office of Corporate Customer Services.

[FR Doc. 2016–19603 Filed 8–16–16; 8:45 am]

BILLING CODE 4910–59–P

DEPARTMENT OF VETERANS AFFAIRS

Privacy Act of 1974

AGENCY: Department of Veterans Affairs (VA).

ACTION: Notice of New System of Records.

SUMMARY: The Privacy Act of 1974 (5 U.S.C. 552(e) (4)) requires that all agencies publish in the **Federal Register** a notice of the existence and character of their systems of records. Notice is hereby given that the Department of Veterans Affairs (VA) is establishing a new system of records entitled "VA National Cemetery Pre-Need Eligibility Determination Records"—VA (SORN # 175VA41A).

DATES: Comments on this new system of records must be received no later than September 16, 2016. If no public comment is received during the period allowed for comment or unless otherwise published in the **Federal Register** by the VA, the new system will become effective September 16, 2016.

ADDRESSES: Written comments concerning the proposed amended system of records may be submitted by: Mail or hand-delivery to Director, Regulations Management (02REG), Department of Veterans Affairs, 810 Vermont Avenue NW., Room 1068, Washington, DC 20420; fax to (202) 273–9026; or email to *www.Regulations.gov.* All comments received will be available for public inspection in the Office of Regulation Policy and Management, Room 1063B, between the hours of 8:00 a.m. and 4:30 p.m., Monday through Friday (except holidays). Please call (202) 461–4902 (this is not a toll-free number) for an appointment. In addition, during the comment period, comments may be viewed online through the Federal Docket Management System (FDMS) at *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: National Cemetery Administration (NCA) Privacy Officer (43D), Department of Veterans Affairs, 810 Vermont Avenue NW., Washington, DC 20420, telephone (202) 632–7728 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION: The proposed system of records contains military service information, entry and discharge documentation, personal identifiers, demographic data (*e.g.,* name, social security number, physical address, phone number, email address), and socioeconomic characteristics (*e.g.,* date of birth, place of birth, date of death, gender, marital records; health records; health related information, benefit related information) provided with an application for a determination of eligibility for burial in a VA national cemetery in advance of an individual's time of need (referred to as "pre-need"). The proposed system of records contains information on Veterans, Veteran beneficiaries, members of the Armed Forces of the United States and their beneficiaries, as well as claimants (such as funeral home directors) submitting pre-need eligibility determinations on behalf of potentially eligible individuals. VA authorized users include VA employees, VA contractors, and other individuals with access to VA IT systems. The purpose of the system of records includes but is not limited to providing a repository for military, personal, and administrative information that is collected, retrieved, and disclosed to authorized individuals related to pre-need eligibility determinations for burial in a VA national cemetery. Information contained in this system of records may also be used as an aggregate, non-personally identifiable set to track, evaluate, and report on local and national benefits initiatives, such as cemetery development and emerging burial needs. Information in this proposed system of records will be protected from unauthorized access through administrative, physical, and technical safeguards. Access to the hard copy and computerized information will be restricted to VA employees and VA contractors by means of PIV card and PIN, and/or passwords. Hard copy records will be maintained in offices that are restricted by cypher locks during work hours and locked after duty hours with security camera surveillance of the office area and facility. The VA facility is located in GSA-leased office space and is under the protection of the Department of Homeland Security.

VA is proposing the following routine use disclosures of information to be maintained in the system:

VA may disclose information from the record of an individual in response to an inquiry from the congressional offices made at the request of that individual or by another on behalf of that individual. VA must be able to provide information about individuals to adequately respond to inquiries from Members of Congress at the request of constituents who have sought their assistance.

VA may, on its own initiative, disclose information from this system to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm. This routine use permits disclosures by the Department to respond to a suspected or confirmed data breach, including conduct of any risk analysis or provision of credit protection services as provided in 38 U.S.C. 5724.

Effective Response. A federal agency's ability to respond quickly and effectively in the event of a breach of federal data is critical to its efforts to prevent or minimize any consequent harm. An effective response necessitates disclosure of information regarding the breach to those individuals affected by it, as well as to persons and entities in a position to cooperate, either by assisting in notification to affected individuals or playing a role in preventing or minimizing harms from the breach.

Disclosure of Information. Often, the information to be disclosed to such persons and entities is maintained by federal agencies and is subject to the Privacy Act (5 U.S.C. 552a). The Privacy Act prohibits the disclosure of any record in a system of records by any means of communication to any person or agency absent the written consent of the subject individual, unless the disclosure falls within one of twelve statutory exceptions. In order to ensure an agency is in the best position to respond timely and effectively, in accordance with 5 U.S.C. 552a(b)(3) of the Privacy Act, agencies should publish a routine use for systems specifically applying to the disclosure of information in connection with response and remedial efforts in the event of a data breach.

VA may, on its own initiative, disclose information in this system, except the names and home addresses of veterans and their dependents, which is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, state, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order. On its own initiative, VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto. VA must be able to provide on its own initiative information that pertains to a violation of laws to law enforcement authorities in order for them to investigate and enforce those laws. Under 38 U.S.C. 5701(a) and (f), VA may only disclose the names and addresses of veterans and their dependents to Federal entities with law enforcement responsibilities. This is distinct from the authority to disclose records in response to a qualifying request from a law enforcement entity, as authorized by Privacy Act subsection 5 U.S.C. 552a(b)(7).

VA may disclose information from this system of records to the Department of Justice (DOJ), either on VA's initiative or in response to DOJ's request for the information, after either VA or DOJ determines that such information is relevant to DoJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

To determine whether to disclose records under this routine use, VA will comply with the guidance promulgated by the Office of Management and Budget in a May 24, 1985, memorandum entitled "Privacy Act Guidance—Update," currently posted at *http://www.whitehouse.gov/omb/inforeg/guidance1985.pdf.* VA must be able to provide information to DoJ in litigation where the United States or any of its components is involved or has an interest. A determination would be made in each instance that under the circumstances involved, the purpose is compatible with the purpose for which VA collected the information. This routine use is distinct from the authority to disclose records in response to a court order under subsection (b)(11) of the Privacy Act, 5 U.S.C. 552(b)(11), or any other provision of subsection (b), in accordance with the court's analysis in *Doe* v. *DiGenova,* 779 F.2d 74, 78–84 (D.C. Cir. 1985) and *Doe* v. *Stephens,* 851 F.2d 1457, 1465–67 (D.C. Cir. 1988).

VA may disclose information from this system of records to individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor, subcontractor, public or private agency, or other entity or individual with whom VA has a contract or agreement to perform services under the contract or agreement. This routine use includes disclosures by an individual or entity performing services for VA to any secondary entity or individual to perform an activity that is necessary for individuals, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to provide the service to VA. This routine use, which also applies to agreements that do not qualify as contracts defined by Federal procurement laws and regulations, is consistent with OMB guidance in OMB Circular A–130, App. I, paragraph 5a(1)(b) that agencies promulgate routine uses to address disclosure of Privacy Act-protected information to contractors in order to perform the services contracts for the agency.

VA may disclose information from this system to the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation. VA must be able to provide information to EEOC to assist it in fulfilling its duties to protect employees' rights, as required by statute and regulation.

VA may disclose information from this system to the Federal Labor Relations Authority (FLRA), including its General Counsel, information related to the establishment of jurisdiction, investigation, and resolution of allegations of unfair labor practices, or in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; for it to address matters properly before the Federal Services Impasses Panel, investigate representation petitions, and conduct or supervise representation elections. VA must be able to provide information to FLRA to comply with the statutory mandate under which it operates.

VA may disclose information from this system to the Merit Systems Protection Board (MSPB), or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law. VA must be able to provide information to MSPB to assist it in fulfilling its duties as required by statute and regulation. VA may disclose information from this system to the National Archives and Records Administration (NARA) and General Services Administration (GSA) in records management inspections conducted under title 44, U.S.C. NARA is responsible for archiving old records which are no longer actively used but may be appropriate for preservation, and for the physical maintenance of the Federal government's records. VA must be able to provide the records to NARA in order to determine the proper disposition of such records.

The notice of intent to publish and an advance copy of the system notice have been sent to the appropriate Congressional committees and to the Director of the Office of Management and Budget (OMB) as required by 5 U.S.C. 552a(r) (Privacy Act) and guidelines issued by OMB (65 FR 77677), December 12, 2000.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, approved this document on August 2, 2016, for publication.

Dated: August 8, 2016.

Kathleen M. Manwell,

Program Analyst, VA Privacy Service, Office of Privacy and Records Management, Department of Veterans Affairs.

SORN 175VA41A

SYSTEM NAME:

VA National Cemetery Pre-Need Eligibility Determination Records—VA.

SYSTEM LOCATION:

Records are maintained at the National Cemetery Scheduling Office (41A1), Suite 200, 4850 Lemay Ferry Road, St. Louis, MO, 63129.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title 38 U.S.C. 2402.

PURPOSE(S):

The purpose for which the records are used will include but will not be limited to the provision of VA burial and memorial benefits; provision of information about VA burial and memorial benefits, including specific claims; determination of eligibility for burial in a VA national cemetery; disclosure of military service information upon request from VA-funded State and Tribal Veterans cemeteries; coordination of committal services and interment upon request of families, funeral homes, and others of eligible decedents at VA national cemeteries; investigation of potential bars to benefits for an otherwise eligible individual. VA will maintain records and information associated with pre-need claims in a recallable system for use at a claimant's time of death and upon receipt of a request for burial in a VA national cemetery for that claimant. Data may also be used at an aggregate non-personally identifiable level to track and evaluate memorial and burial benefit initiatives.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

The records contain information on Veterans, family members of Veterans, Members of the Armed Forces (Servicemembers), family members of Servicemembers, Reservists and Retirees (Active Duty; Reserves; or National Guard), and other VA customers (*e.g.*, attorneys, agents, Veterans Service Organizations, funeral directors, coroners, Missing in America Project (MIAP) volunteers, State and local governmental administrators, in addition to VA authorized users permitted by VA to access VA IT systems (*e.g.*, VA employees, VA contractors, VA registered volunteers).

CATEGORIES OF RECORDS IN THE SYSTEM:

Records may include information submitted to VA by means of paper or online forms that respondents can mail or electronically transmit by fax or email for storage and retrieval in VA's secure filing and IT systems. Records may contain information, such as demographics and personal identifiers (*e.g.* names, mailing addresses, email addresses, phone numbers, social security numbers, VA claim numbers and military service numbers); socioeconomic characteristics (*e.g.*, date of birth, place of birth, date of death, gender, marital records; health records; health related information, benefit related information); military service information (*e.g.*, dates of active duty, dates of active duty for training, military service numbers, branch of service including Reserves or National Guard service, locations of service for National Guard, dates of entry, enlistment, or discharge, type and character of discharge, rank, awards, decorations, and other military history and information).

Records may also include supporting documentation submitted to identify individuals submitting pre-need applications on behalf of claimants. Supporting documentation may include, but is not limited to the following items: VA Form 21–22 (Appointment of Veterans Service Organization as Claimant's Representative), VA Form 21–22a (Appointment of Individual as Claimant's Representative) for an Authorized Attorney, or Agent; proof of prior written authorization, such as a durable power of attorney, or an affidavit establishing a caregiver relationship to the claimant (spousal, parent, other relative); and documentation showing the individual as the court-appointed representative authorized to act on behalf of as the claimant.

RECORD SOURCE CATEGORIES:

Information in this system of records is provided by Veterans; Veteran beneficiaries; members of the Armed Forces of the United States including Reserves and National Guard and their beneficiaries, as well as other individuals (such as funeral home directors) submitting pre-need eligibility determinations on behalf of claimants; VA employees; other VA authorized users (*e.g.*, Department of Defense), VA IT systems and databases; VA claims records; and official military records IT systems.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. VA may disclose information from the record of an individual in response to an inquiry from the congressional office made at the request of that individual. VA must be able to provide information about individuals to adequately respond to inquiries from Members of Congress at the request of constituents who have sought their assistance. VA may also disclose information to other Federal, state and local, tribal or foreign government agencies to assists with verifying military service for the purpose of providing a benefit.

2. VA may, on its own initiative, disclose information from this system to appropriate agencies, entities, and persons when (1) VA suspects or has confirmed that the integrity or confidentiality of information in the system of records has been compromised; (2) the Department has determined that as a result of the suspected or confirmed compromise there is a risk of embarrassment or harm to the reputations of the record subjects, harm to economic or property interests, identity theft or fraud, or harm to the security, confidentiality, or integrity of this system or other systems or programs (whether maintained by the Department or another agency or entity) that rely upon the potentially compromised information; and (3) the disclosure is to agencies, entities, or persons whom VA determines are reasonably necessary to assist or carry out the Department's efforts to respond to the suspected or confirmed compromise and prevent, minimize, or remedy such harm.

3. VA may, on its own initiative, disclose information in this system, except the names and home addresses of veterans and their dependents, which is relevant to a suspected or reasonably imminent violation of law, whether civil, criminal or regulatory in nature and whether arising by general or program statute or by regulation, rule or order issued pursuant thereto, to a Federal, state, local, tribal, or foreign agency charged with the responsibility of investigating or prosecuting such violation, or charged with enforcing or implementing the statute, regulation, rule or order. On its own initiative, VA may also disclose the names and addresses of veterans and their dependents to a Federal agency charged with the responsibility of investigating or prosecuting civil, criminal or regulatory violations of law, or charged with enforcing or implementing the statute, regulation, rule or order issued pursuant thereto.

4. VA may disclose information from this system of records to the Department of Justice (DOJ), either on VA's initiative or in response to DOJ's request for the information, after either VA or DOJ determines that such information is relevant to DOJ's representation of the United States or any of its components in legal proceedings before a court or adjudicative body, provided that, in each case, the agency also determines prior to disclosure that release of the records to the DOJ is a use of the information contained in the records that is compatible with the purpose for which VA collected the records. VA, on its own initiative, may disclose records in this system of records in legal proceedings before a court or administrative body after determining that the disclosure of the records to the court or administrative body is a use of the information contained in the records that is compatible with the purpose for which VA collected the records.

5. VA may disclose information from this system of records to individuals, U.S. Military Service Departments, organizations, private or public agencies, or other entities or individuals with whom VA has a contract or agreement to perform such services as VA may deem practicable for the purposes of laws administered by VA, in order for the contractor, subcontractor, public or private agency, or other entity or individual with whom VA has a contract or agreement to perform services under the contract or agreement.

6. VA may disclose information from this system to the Equal Employment Opportunity Commission (EEOC) when requested in connection with investigations of alleged or possible discriminatory practices, examination of Federal affirmative employment programs, or other functions of the Commission as authorized by law or regulation.

7. VA may disclose information from this system to the Federal Labor Relations Authority (FLRA), including its General Counsel, information related to the establishment of jurisdiction, investigation, and resolution of allegations of unfair labor practices, or in connection with the resolution of exceptions to arbitration awards when a question of material fact is raised; for it to address matters properly before the Federal Services Impasses Panel, investigate representation petitions, and conduct or supervise representation elections.

8. VA may disclose information from this system to the Merit Systems Protection Board (MSPB), or the Office of the Special Counsel, when requested in connection with appeals, special studies of the civil service and other merit systems, review of rules and regulations, investigation of alleged or possible prohibited personnel practices, and such other functions promulgated in 5 U.S.C. 1205 and 1206, or as authorized by law.

9. VA may disclose information from this system to the National Archives and Records Administration (NARA) and General Services Administration (GSA) in records management inspections conducted under title 44, U.S.C.

10. VA may disclose information from this system of records upon request from funeral homes participating in NCA committal services, burials, and other memorial services, family members in need of military service documentation related to a pre-need claim, and VA-funded State and Tribal Veteran cemeteries seeking military service documentation.

POLICIES AND PRACTICES FOR STORAGE OF RECORDS:

Records in this system are maintained in paper and electronic formats in the NCA National Cemetery Scheduling Office. Records are maintained on electronic storage media including magnetic tape, disk, and laser optical media.

POLICIES AND PRACTICES FOR RETRIEVABILITY OF RECORDS:

Information is retrievable by the use of name only; name and one or more numbers (service or social security); name and one or more criteria (*e.g.,* date of birth or dates of service); VA claim number; or other VA or NCA assigned identifier.

POLICIES AND PRACTICES FOR RETENTION AND DISPOSAL OF RECORDS:

Records are retained in accordance with records retention standards approved by the Archivist of the United States, the National Archives and Records Administration, and published in the Agency Records Control Schedules. Paper records are destroyed by shredding at the time of disposition, and automated storage media is retained and disposed of in accordance with disposition authorization approved by the Archivist of the United States.

PHYSICAL, PROCEDURAL, AND ADMINISTRATIVE SAFEGUARDS:

Information in the system is protected from unauthorized access through administrative, physical, and technical safeguards. Access to the hard copy and computerized information is restricted to authorized VA employees and VA contractors by means of PIV card and PIN, and/or passwords. Information security officers and system data stewards review and authorize data access requests. VA regulates data access with security software that authenticates users and requires individually unique codes and passwords. VA requires information security training for all staff and instructs staff on the responsibility each person has for safeguarding data confidentiality. Hard copy records are maintained in offices that are restricted by cypher locks during work hours, and locked after duty hours with security camera surveillance of the office area and facility.

SYSTEM MANAGER(S) AND ADDRESS:

The Official maintaining this system of records and responsible for policies and procedures is the Director (41A1), National Cemetery Scheduling Office, Suite 200, 4850 Lemay Ferry Road, St. Louis, MO 63129.

RECORD ACCESS PROCEDURES:

Individuals seeing information regarding access to and contesting of records in this system may write or call the NCA Privacy Officer, (43D), National Cemetery Administration, 810 Vermont Avenue NW., Washington, DC 20420.

CONTESTING RECORD PROCEDURES:

See Record Access Procedures above.

NOTIFICATION PROCEDURE:

Individuals who wish to determine whether this system of records contains information about them should contact the NCA Privacy Officer (43D), National Cemetery Administration, 810 Vermont Avenue NW., Washington, DC 20420. Inquiries should include as much of the following information to identify the record: Individual's full name, social security number, individual's return address.

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

None.

[FR Doc. 2016–19591 Filed 8–16–16; 8:45 am]

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Part II

Department of Energy

10 CFR Parts 429 and 431

Energy Conservation Program: Test Procedure for Walk-in Coolers and Walk-in Freezers; Proposed Rule

DEPARTMENT OF ENERGY

10 CFR Parts 429 and 431

[Docket No. EERE–2016–BT–TP–0030]

RIN 1904–AD72

Energy Conservation Program: Test Procedure for Walk-in Coolers and Walk-in Freezers

AGENCY: Office of Energy Efficiency and Renewable Energy, Department of Energy.

ACTION: Notice of proposed rulemaking and announcement of public meeting.

SUMMARY: This document proposes amending the test procedure for certain walk-in cooler and freezer components by improving the procedure's clarity, updating related certification and enforcement provisions to address the performance-based energy conservation standards for walk-in cooler and freezer equipment, and establishing labeling requirements to aid manufacturers in determining which components would be considered for compliance purposes as intended for walk-in cooler and freezer applications. The proposed amendments consist of certain walk-in cooler and freezer refrigeration system-specific provisions, including product-specific definitions, removal of the test method for systems with hot gas defrost, and a method to accommodate refrigeration equipment that use adaptive defrost and on-cycle variable-speed evaporator fan control.

DATES: *Comments:* DOE will accept comments, data, and information regarding this notice of proposed rulemaking (NOPR) before and after the public meeting, but no later than October 17, 2016. See section V, "Public Participation," for details.

DOE will hold a public meeting on Monday, September 12, 2016, from 9:30 a.m. to 12:30 p.m., in Washington, DC. The meeting will also be broadcast as a webinar. See section V, "Public Participation," for webinar registration information, participant instructions, and information about the capabilities available to webinar participants.

ADDRESSES: The public meeting will be held at the U.S. Department of Energy, Forrestal Building, Room 4A–104, 1000 Independence Avenue SW., Washington, DC 20585.

Any comments submitted must identify the Test Procedure NOPR for Walk-in Coolers and Walk-in Freezers, and provide docket number EERE–2016–BT–TP–0030 and/or regulatory information number (RIN) number 1904–AD72. Comments may be submitted using any of the following methods:

(1) *Federal eRulemaking Portal: www.regulations.gov.* Follow the instructions for submitting comments.

(2) *Email: WICF2016TP0030@ee.doe.gov.* Include the docket number and/or RIN in the subject line of the message.

(3) *Mail:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, Mailstop EE–5B, 1000 Independence Avenue SW., Washington, DC 20585–0121. If possible, please submit all items on a compact disc (CD), in which case it is not necessary to include printed copies.

(4) *Hand Delivery/Courier:* Appliance and Equipment Standards Program, U.S. Department of Energy, Building Technologies Office, 950 L'Enfant Plaza SW., 6th Floor, Washington, DC 20024. Telephone: (202) 586–6636. If possible, please submit all items on a CD, in which case it is not necessary to include printed copies.

For detailed instructions on submitting comments and additional information on the rulemaking process, see section V of this document (Public Participation).

DOCKET: The docket, which includes **Federal Register** notices, public meeting attendee lists and transcripts, comments, and other supporting documents/materials, is available for review at *www.regulations.gov.* All documents in the docket are listed in the *www.regulations.gov* index. However, some documents listed in the index, such as those containing information that is exempt from public disclosure, may not be publicly available.

The docket Web page can be found at *http://www.regulations.gov/#!docketDetail;D=EERE-2016-BT-TP-0030.* The docket Web page will contain simple instructions on how to access all documents, including public comments, in the docket. See section V for information on how to submit comments through *www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT:

Ms. Ashley Armstrong, U.S. Department of Energy, Office of Energy Efficiency and Renewable Energy, Building Technologies Office, EE–2J, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–6590. Email: *Ashey.Armstrong@ee.doe.gov.*

Mr. Michael Kido, U.S. Department of Energy, Office of the General Counsel, GC–33, 1000 Independence Avenue SW., Washington, DC 20585–0121. Telephone: (202) 586–8145. Email: *Michael.Kido@hq.doe.gov.*

For further information on how to submit a comment, review other public comments and the docket, or participate in the public meeting, contact the Appliance and Equipment Standards Program staff at (202) 586–6636 or by email: *WICF2016TP0030@ee.doe.gov.*

SUPPLEMENTARY INFORMATION: DOE proposes to incorporate by reference the following industry standards into 10 CFR part 431:

(1) AHRI Standard 420–2008 ("AHRI 420–2008"), "Performance Rating of Forced-Circulation Free-Delivery Unit Coolers for Refrigeration," approved 2008.

(2) AHRI Standard 1250–2009 ("AHRI 1250–2009"), "Standard for Performance Rating of Walk-in Coolers and Freezers," approved 2009.

(3) ASHRAE Standard 23.1–2010 ("ASHRAE 23.1–2010"), "Methods of Testing for Rating the Performance of Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant," approved 2010.

(4) ASTM C518–04 ("ASTM C518"), Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus, approved May 1, 2004.

Copies of AHRI Standard 420–2008 and AHRI Standard 1250–2009 may be purchased from AHRI at 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, or by going to *http://www.ahrinet.org.*

Copies of ASHRAE 23.1–2010 may be purchased from ASHRAE at 1971 Tullie Circle NE., Atlanta, GA 30329, or by going to *http://www.ashrae.org.*

Copies of ASTM C518 may be obtained from the American Society for Testing and Materials, 100 Barr Harbor Drive, West Conshohocken, PA 19428–2959, (610) 832–9500, or *http://www.astm.org.*

See section IV.M for a further discussion of these standards.

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I. Authority and Background

Walk-in coolers and walk-in freezers (collectively, "walk-ins" or "WICFs") are included in the list of "covered equipment" for which the U.S. Department of Energy ("DOE" or "the Department") is authorized to establish and amend energy conservation standards and test procedures. (42 U.S.C. 6311(1)(G)) A walk-in is defined as an enclosed storage space of less than 3,000 square feet that can be walked into and is refrigerated to prescribed temperatures based on whether the given unit is a cooler or a freezer. See generally 42 U.S.C. 6311(20). In simple terms, a walk-in is an insulated box (or envelope) serviced by a refrigerated system that feeds cold air to the box's interior. DOE's energy conservation standards and test procedures for walk-ins are currently prescribed at 10 CFR 431.306 and 10 CFR 431.304, respectively. The following sections discuss DOE's authority to establish test procedures and certification requirements for walk-ins and relevant background information regarding DOE's consideration of test procedures and certification requirements for this equipment.

A. Authority

Title III, Part C[1] of the Energy Policy and Conservation Act of 1975 ("EPCA" or, in context, "the Act"), Public Law 94–163 (codified as 42 U.S.C. 6311–6317, as codified) established the Energy Conservation Program for Certain Industrial Equipment, a program covering certain industrial equipment, including walk-ins, the subject of this document. (42 U.S.C. 6311(1)(G))

In general, this program addresses the energy efficiency of certain types of commercial and industrial equipment. Relevant provisions of the Act specifically include definitions (42 U.S.C. 6311), energy conservation standards (42 U.S.C. 6313), test procedures (42 U.S.C. 6314), labelling provisions (42 U.S.C. 6315), and the authority to require information and reports from manufacturers (42 U.S.C. 6316). Manufacturers of covered equipment must use the prescribed DOE test procedure as the basis for making representations to the public regarding the energy use or efficiency of such equipment. (42 U.S.C. 6314(d))

Under 42 U.S.C. 6293, EPCA sets forth the criteria and procedures DOE must follow when prescribing or amending test procedures for covered products. EPCA provides in relevant part that any test procedures prescribed or amended under this section shall be reasonably designed to produce test results which measure energy efficiency, energy use or estimated annual operating cost of a covered product during a representative average use cycle or period of use and shall not be unduly burdensome to conduct. See 42 U.S.C. 6293(b)(3) and 42 U.S.C. 6316(a) (applying 42 U.S.C. 6293 to walk-ins).

In addition, if DOE determines that a test procedure amendment is warranted, it must publish proposed test procedures and offer the public an opportunity to present oral and written comments on them. (42 U.S.C. 6293(b)(2)) Finally, in any rulemaking to amend a test procedure, DOE must determine to what extent, if any, the proposed test procedure would alter the measured energy efficiency of any covered product as determined under the existing test procedure. (42 U.S.C. 6293(e)(1))

If adopted, manufacturers would be required to use the proposed test procedure and metric when making representations regarding the energy use of covered equipment 180 days after the publication date of any final rule for those walk-in cooler and walk-in freezers that are addressed by the test procedure. (42 U.S.C. 6314(d))

DOE anticipates proposing amended energy conservation standards for certain classes of refrigeration systems for walk-ins in a separate rulemaking. See Docket No. EERE–2015–BT–STD–0016.

B. Background

Section 312 of the Energy Independence and Security Act of 2007, Public Law 110–140 (December 19, 2007), required DOE to establish test procedures to measure the energy use of walk-in coolers and walk-in freezers. On April 15, 2011, DOE published test procedures for the principal components that make up a walk-in: The panels, doors, and refrigeration systems. DOE took this component-based testing approach based on a significant body of feedback from interested parties that requiring a single test procedure for an entire walk-in would be impractical because most walk-ins are assembled on-site with components from different manufacturers. 76 FR 21580, 21582 (April 15, 2011).

On February 20, 2014, DOE initiated another test procedure rulemaking for walk-ins to clarify and modify the test procedures published in April 2011. DOE also proposed to revise the existing regulations for walk-ins to allow manufacturers to use an alternative efficiency determination method ("AEDM") to certify compliance and report ratings, after meeting certain qualifications. DOE published a supplemental notice of proposed rulemaking ("SNOPR) on February 20, 2014, soliciting public comments, data, and information on the test procedure modifications. 79 FR 9818. DOE published a final rule codifying the test procedure and AEDM provisions for walk-ins on May 13, 2014. 79 FR 27388.

DOE also published a notice of proposed rulemaking ("NOPR") to create new performance-based energy conservation standards for walk-ins on September 11, 2013. ("September 2013 NOPR") 78 FR 55782. That NOPR addressed the comments received in earlier stages of the rulemaking and proposed new energy conservation standards. In conjunction with the September 2013 NOPR, DOE published a technical support document ("TSD") to accompany the proposed rule along with engineering analysis spreadsheets, the government regulatory impact model ("GRIM") spreadsheet, the life cycle cost ("LCC") spreadsheet, and the national impact analysis ("NIA") spreadsheet. See Docket No. EERE–2008–BT–STD–0015. DOE proposed standards for eight dedicated condensing classes of refrigeration systems, two multiplex condensing classes of refrigeration systems, three classes of panels, four classes of non-display doors, and two classes of display doors. (The refrigeration system standards use the metric "annual walk-in energy factor ("AWEF"), and the door standards use an energy use metric that incorporates thermal insulating ability and electrical energy used by the door. The panel standards are equivalent to those previously established and use a measurement of thermal insulation—or "R-value"—to represent the energy efficiency of these components.) DOE published a final rule adopting these new standards on June 3, 2014. 79 FR 32050. Except for the equipment classes whose standards have been vacated, as described below, compliance with the standards adopted in the June 2014 final rule is required starting on June 5, 2017.

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[1] For editorial reasons, upon codification in the U.S. Code, Part C was redesignated Part A–1.

After publication of the 2014 Final Rule, the Air-Conditioning, Heating and Refrigeration Institute ("AHRI") and Lennox International, Inc. (a manufacturer of walk-in refrigeration systems) filed petitions for review of DOE's final rule and DOE's subsequent denial of a petition for reconsideration of the rule (79 FR 59090 (October 1, 2014)) with the United States Court of Appeals for the Fifth Circuit. *Lennox Int'l, Inc.* v. *Dep't of Energy,* Case No. 14–60535 (5th Cir.). Other walk-in refrigeration system manufacturers—Rheem Manufacturing Co. (owner of Heat Transfer Products Group) and Hussmann Corp.—along with the Air Conditioning Contractors of America (a trade association representing contractors who install walk-in refrigeration systems) intervened on the petitioners' behalf, while the Natural Resources Defense Council ("NRDC")—representing itself, the American Council for an Energy-Efficient Economy, and the Texas Ratepayers' Organization to Save Energy—intervened on behalf of DOE. As a result of this litigation, a settlement agreement was reached to address, among other things, six of the refrigeration system standards—the standards for low-temperature dedicated condensing equipment classes and both medium- and low-temperature multiplex condensing equipment classes.

A controlling court order from the United States Court of Appeals for the Fifth Circuit, issued on August 10, 2015, vacated those six standards. On November 12, 2015, DOE amended the CFR to reflect this order. As for the remaining standards promulgated by the June 2014 final rule—*i.e.* the (1) four standards applicable to dedicated condensing refrigeration systems operating at medium-temperatures, (2) three standards applicable to panels, and (3) six standards applicable to doors—these standards were not vacated and remain subject to the June 5, 2017 compliance date prescribed in the June 2014 final rule. See 79 FR at 32051–32052 (Table I.1) and 32123–32124 (codified at 10 CFR 431.306(a), (c)–(e)).

To address the vacated standards, DOE established a working group to negotiate proposed energy conservation standards to replace them. Specifically, on August 5, 2015, DOE published a notice of intent to establish a Working Group for Certain Equipment Classes of Refrigeration Systems of Walk-in Coolers and Freezers to Negotiate a Notice of Proposed Rulemaking for Energy Conservation Standards ("Working Group"). 80 FR 46521. The Working Group was established under the Appliance Standards and Rulemaking Federal Advisory Committee ("ASRAC") in accordance with the Federal Advisory Committee Act ("FACA") and the Negotiated Rulemaking Act ("NRA"). (5 U.S.C. App. 2; 5 U.S.C. 561–570, Public Law 104–320.) The purpose of the Working Group was to discuss and, if possible, reach consensus on proposed standard levels for the energy efficiency of the affected classes of walk-in refrigeration systems. The Working Group consisted of 12 representatives of parties having a defined stake in the outcome of the proposed standards and one DOE representative (see Table 1). The Working Group consulted as appropriate with a range of experts on technical issues. The Working Group met in-person during 13 days of meetings held between August 27 and December 15, 2015.

TABLE 1—WALK-IN REFRIGERATION SYSTEMS NEGOTIATED RULEMAKING WORKING GROUP

Full Name	Affiliation
Ashley Armstrong	U.S. Department of Energy.
Lane Burt	Natural Resources Defense Council.
Mary Dane	Traulsen.
Cyril Fowble	Lennox International, Inc.
Sean Gouw	CA Investor-Owned Utilities.
Andrew Haala	Hussmann Corp.
Armin Hauer	ebm-papst, Inc.
John Koon	Manitowoc Company.
Joanna Mauer	Appliance Standards Awareness Project.
Charlie McCrudden	Air Conditioning Contractors of America.
Louis Starr	Northwest Energy Efficiency Alliance.
Michael Straub	Rheem Manufacturing.
Wayne Warner	Emerson Climate Technologies.

On December 15, 2015, the Working Group reached consensus on, among other things, a series of energy conservation standards to replace those that were vacated as a result of the litigation. The Working Group assembled their recommendations into a single Term Sheet (See Docket EERE–2015–BT–STD–0016, No. 0052) that was presented to, and approved by the ASRAC on December 18, 2015. DOE anticipates proposing to adopt in a separate rulemaking document energy conservation standards consistent with the Working Group's Term Sheet for those classes of walk-in refrigeration systems whose standards were vacated. See Docket No. EERE–2015–BT–STD–0016 for all background documents on the negotiated rulemaking.

While the Working Group's focus centered primarily on addressing the six energy conservation standards for low-temperature dedicated condensing equipment classes and both medium- and low-temperature multiplex condensing equipment classes, (see Docket No. EERE–2015–BT–STD–0016, No. 0001 and 0002), the Term Sheet also included recommendations that DOE consider making certain amendments involving the test procedure. These recommendations addressed technical corrections to the test procedure itself; definitions for certain terms to provide clarity regarding the applicability of the standards (and, relatedly, the test procedure); and other test procedure changes that the Working Group deemed necessary in order to implement the agreed-upon refrigeration system standards.[2] DOE considered the approved Term Sheet, along with other comments received during the negotiated rulemaking process, in developing several of the test procedure amendments that this document proposes to adopt.

II. Synopsis of the Notice of Proposed Rulemaking

The proposed provisions fall into two groups. The first group consists of test procedure modifications and other additions to the regulatory text recommended by the Working Group and listed in the Term Sheet, including:

—Adding definitions for the terms "dedicated condensing unit," "dedicated condensing refrigeration system," "packaged dedicated system," "matched condensing unit," "matched refrigeration system," "outdoor dedicated condensing refrigeration system," "indoor dedicated condensing refrigeration system," "adaptive defrost," "process cooling," "preparation room refrigeration," and "refrigerated storage space," and modifying the definition of "refrigeration system;"

—Removing the method for calculating defrost energy and defrost heat load of a system with hot gas defrost; and

—Establishing a regulatory approach for refrigeration systems with adaptive defrost and/or on-cycle variable-speed evaporator fan control, that would require demonstration of compliance with the standard for any such unit to be based on testing without activation of these features, while allowing for representations of their improved performance when using these features.

The second group of proposed provisions consists of test procedure modifications and certification, compliance, and enforcement provisions that, while not part of the Term Sheet, are necessary for implementing the energy conservation standards. This group of proposed changes includes:

—Re-organizing the test procedure provisions in 10 CFR 431.304 for improved clarity, and correcting typographical errors in the rule language;

—Clarifying section 3.0 "Additional Definitions" in appendix A to subpart R of part 431;

—Modifying the current walk-in certification and reporting requirements in 10 CFR 429.53 to clarify applicability of walk-in test procedures to certain equipment classes and add provisions for reporting additional rating metrics;

—Adding walk-in refrigeration systems, panels, and doors to the list of products and equipment included as part of the enforcement testing requirements prescribed in 10 CFR 429.110(e)(2); and

—Adding labeling requirements for walk-in refrigeration systems, panels, and doors.

III. Discussion

This proposal stems from the detailed discussions and suggestions offered by Working Group participants during the walk-in negotiated rulemaking. These participants, in addition to providing detailed feedback for consideration in developing the energy conservation standards to replace those that were vacated, also offered detailed recommendations regarding the walk-in test procedures. These recommendations were offered as a means to address questions related to the treatment of certain types of features or components that may be present in a given walk-in refrigeration system. These aspects of the proposal, along with other elements involving the implementation of DOE's certification and labeling requirements and general obligations under EPCA, are addressed in the sections that follow. While DOE seeks comment regarding all aspects of its proposal, section V.E includes a detailed list of specific issues on which DOE seeks comment.

A. Actions in Response to ASRAC Negotiated Terms

1. Definitions

The Working Group recommended that DOE define the terms "dedicated condensing unit," "matched condensing unit," and "outdoor condensing unit" (Term Sheet at EERE–2015–BT–STD–0016, No. 0056, recommendation #1); "adaptive defrost" (Term Sheet at EERE–2015–BT–STD–0016, No. 0056, recommendation #2); and "process cooling," "preparation room refrigeration," and "storage space" (Term Sheet at EERE–2015–BT–STD–0016, No. 0056, recommendation #7). DOE is also proposing to define the terms "dedicated condensing refrigeration system," "outdoor dedicated condensing refrigeration system," "indoor dedicated condensing refrigeration system," "matched refrigeration system," "unit cooler," and "packaged dedicated system" to supplement the Working Group-recommended definitions. These supplemental definitions were developed to help enhance the clarity of the walk-in regulatory framework and to assist manufacturers in readily ascertaining how to classify (and certify for compliance purposes) the myriad of refrigeration systems they produce. Finally, DOE is proposing to modify the current definition of refrigeration system to align it more closely with the terminology being defined here. The following sections address DOE's proposed definitions, all of which would appear in 10 CFR 431.302, if adopted. (The precise text for each of these definitions appears under the proposed regulatory text appearing at the end of this document.)

a. Dedicated Condensing Unit and Dedicated Condensing Refrigeration System

In the June 2014 final rule, DOE divided refrigeration systems into classes based on their treatment under the test procedure with respect to condensing unit configuration. 79 FR at 32069–32070. (denoting "dedicated condensing" equipment class standards as applying to systems consisting of (a) a dedicated condensing unit and a unit cooler, (b) a single-package system that includes an entire refrigeration system, and (c) stand-alone dedicated condensing units.) In a related test procedure final rule, DOE also revised the regulatory approach for dedicated condensing walk-in refrigeration systems by specifying that in those instances where a complete walk-in refrigeration system consists of a unit cooler and condensing unit that are sourced from separate manufacturers, each of those manufacturers (*i.e.,* original equipment manufacturer or "OEM") is responsible for certifying the compliance of their respective components. See 79 FR 27388 (May 13, 2014) ("May 2014 test procedure rule"). Under this approach, the entity that combines and sells the matched-pair system consisting of the separately-sourced unit cooler and dedicated condensing unit need only ensure that the unit cooler and condensing unit, by themselves, have been certified by their respective manufacturers to meet the relevant energy conservation standard. The May 2014 test procedure rule also adopted testing methods to enable an OEM to readily test and rate a condensing unit individually.

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[2] The recommended changes to the test procedure deal exclusively with efficiency measurement and certification for the classes of refrigeration systems that were the subject of the negotiations, and do not affect the test procedures for the refrigeration system standards that were not vacated. They specifically address removing test procedure provisions for hot gas defrost and requiring that certified efficiency levels for comparison to the standards for evaluation of compliance would not make use of the test procedure provisions for adaptive defrost or on-cycle variable-speed evaporator fans.

Proper classification of condensing units by type is important because DOE has consistently held that the condensers and compressors of a multiplex condensing system are *not* covered by walk-in regulations. (See the September 2013 NOPR, 78 FR at 55801; see also Docket No. EERE–2011–BT–TP–0024, DOE, Public Meeting Transcript (October 22, 2014), No. 0117 at p. 21) DOE has not previously defined either dedicated condensing unit or multiplex condensing equipment, and the Working Group recommended defining the former to clarify what equipment would be subject to condensing unit standards. Thus, as part of the negotiated terms, the Working Group recommended that DOE codify a definition for "dedicated condensing unit." (See Term Sheet, Docket No. EERE–2015–BT–STD–0016, No. 0056, Recommendation #1)

During the Working Group negotiation meetings, participants discussed several factors that may distinguish dedicated condensing equipment from multiplex condensing equipment. First, the Working Group discussed the components found in a dedicated condensing unit. Lennox recommended that a dedicated condensing unit should be a factory-made assembly that includes one or more compressors, a condenser, and one refrigeration circuit. (Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (October 16, 2015), No. 0063 at pp. 247–248) Lennox also clarified that it considered a single package refrigeration system (that is, a factory-made assembly consisting of one or more compressors, a condenser, and an evaporator) to be a type of dedicated condensing system. (Docket No. EERE–2015–BT–STD–0016, DOE and Lennox, Public Meeting Transcript (October 16, 2015), No. 0063 at pp. 249–251)

Second, the Working Group discussed how to treat a single assembly with multiple compressors and/or condensers. Lennox recommended that the definition also specify that a dedicated condensing system is designed to serve one refrigerated load. (Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (October 16, 2015), No. 0063 at pp. 247–248) Hussmann also noted that a dedicated condensing unit could be packaged with other dedicated condensing units, but could still be covered as long as the individual unit has one refrigeration circuit. (Docket No. EERE–2015–BT–STD–0016, Hussmann, Public Meeting Transcript (October 16, 2015), No. 0063 at pp. 253–254) Lennox then clarified that, in its view, a single, stand-alone condensing unit would be considered a dedicated condensing unit, but so would a unit with multiple independent circuits, as well as systems with parallel pipe systems that serve one load. However, a unit with a common condenser coil with multiple refrigeration inlets would not be considered as a dedicated condensing unit. (Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (October 16, 2015), No. 0063 at pp. 256–257)

The proposed dedicated condensing equipment class definition addresses three refrigeration system configurations—(1) a dedicated condensing unit; (2) a packaged dedicated system; and (3) a matched refrigeration system. To emphasize this three-pronged approach, DOE proposes defining what a dedicated condensing refrigeration system is to clarify the scope of this equipment class. Consistent with Lennox's assertion that single package refrigeration systems are a type of dedicated condensing system, DOE is proposing to include this configuration in the proposed definition. DOE also proposes that a matched condensing system—consisting of a dedicated condensing unit that is distributed in commerce with one or more specific unit coolers—would also be treated as a kind of dedicated condensing system. (The following two sections discuss packaged dedicated systems and matched systems in more detail.) Finally, DOE proposes to include in the definition that a dedicated condensing system could consist of a dedicated condensing unit sold separately from any unit cooler. This proposed clarification underpins DOE's certification approach of allowing manufacturers to test and rate condensing units separately to certify compliance with the dedicated condensing standard, without having to distribute their condensing units in commerce with one or more specific unit coolers.

Each of these elements is reflected in DOE's proposed definition for "dedicated condensing unit," which would require such a unit be a positive displacement condensing unit that is part of a refrigeration system (as defined in 10 CFR 431.302) and is an assembly that (1) includes 1 or more compressors, a condenser, and one refrigeration circuit and (2) is designed to serve one refrigerated load.

This definition omits the term "factory-made" from the definition to avoid suggesting that such an assembly is not a condensing unit (and thus not covered by DOE regulations) if it happens to be assembled from its subcomponents after shipment from the factory.

Additionally, for the reasons discussed in this preamble, DOE is proposing to define "dedicated condensing refrigeration system" as referring to a (a) dedicated condensing unit, (b) packaged dedicated system, or (c) matched refrigeration system.

DOE notes that the proposed definition would encompass a dedicated condensing system that may be part of an assembly or package that includes other equipment—an approach that is consistent with Hussmann's comment discussed earlier.

DOE requests comment on the proposed definitions for dedicated condensing unit and dedicated condensing refrigeration system.

b. Packaged Dedicated System

DOE is proposing to treat a packaged dedicated system as a type of dedicated condensing refrigeration system. These systems are factory-assembled equipment where the components serving the compressor, condenser, and evaporator functions are "packaged" into a single piece of equipment. The system is then installed as part of a walk-in application with the compressor and condenser located on the outside of the walk-in envelope (*i.e.,* the boxed storage enclosure) and the evaporator on the inside. (When using such a system, the walk-in insulated enclosure is manufactured with a hole in the wall or ceiling in which the packaged system is mounted.) The use of this equipment is necessarily limited to small-capacity walk-ins due to load-bearing limitations of the walk-in envelope. DOE is proposing to define "packaged dedicated systems" by combining elements of the proposed definition for "dedicated condensing unit" (see section III.A.1.a) and the definition for "forced-circulation free-delivery unit cooler (unit cooler)" from AHRI–1250–2009. Consequently, DOE is proposing to define a "packaged dedicated system" as "a refrigeration system (as defined in 10 CFR 431.302) that is a single-package assembly that includes one or more compressors, a condenser, a means for forced circulation of refrigerated air, and elements by which heat is transferred from air to refrigerant, without any element external to the system imposing resistance to flow of the refrigerated air."

DOE requests comment on the proposed definition for packaged dedicated system.

c. Matched Condensing Unit and Matched Refrigeration System

During one of the initial Working Group meetings, DOE offered for consideration a definition for a matched condensing unit—specifically, to define this term as "a dedicated condensing unit that is distributed in commerce with one or more specific unit coolers." (Docket No. EERE–2015–BT–STD–0016, DOE, Public Meeting Transcript (October 15, 2015), No. 0062 at p. 138–139) In offering this definition, DOE intended to distinguish a matched condensing unit from an individually-sold condensing unit for testing purposes. (This distinction is critical since a matched system could be tested using the currently prescribed test method from AHRI 1250–2009 for variable-speed compressors, while an individually-sold dedicated condensing unit could not). The Working Group later recommended a modified version of this definition to indicate that the unit coolers matched to the condensing unit would be specified by the condensing unit manufacturer. That modified definition, which DOE is proposing to include as part of 10 CFR 431.302, would define a "matched condensing unit" as "a dedicated condensing unit that is distributed in commerce with one or more unit cooler(s) specified by the condensing unit manufacturer."

For completeness, DOE is also proposing to define "matched refrigeration system" (also called "matched pair") as "a refrigeration system including the matched condensing unit and the one or more unit coolers with which it is distributed in commerce."

DOE requests comments on the proposed definitions for matched condensing unit and matched refrigeration system.

d. Outdoor and Indoor Dedicated Condensing Refrigeration Systems

DOE currently distinguishes the dedicated condensing refrigeration system classes based on whether the condensing unit is located indoors or outdoors. 79 FR at 32069–32070. Building on this established foundation, DOE is proposing definitions for the terms "outdoor dedicated condensing refrigeration system" and "indoor dedicated condensing refrigeration system" to distinguish these classes of equipment for standards and rating purposes. Because outdoor systems are tested differently and generally have very different measured AWEF values than indoor systems, DOE believes that these class distinctions should be clearly defined.

In developing these definitions, DOE relied on the fact that outdoor condensing units use an outer casing to protect the unit's internal components from weather-related elements. During the negotiated rulemaking meetings, AHRI suggested that DOE include in the definition the phrase, "designed to be installed and operated outside the building envelope" so that adding a casing to a unit designed to be an indoor condensing unit (*e.g.,* for purposes of fan protection) would not cause DOE to consider it as an outdoor condensing unit. (Docket No. EERE–2015–BT–STD–0016, AHRI, Public Meeting Transcript (December 15, 2015), No. 0060 at p. 137) DOE asked AHRI to identify design differences that could help DOE determine whether a certain condensing unit is designed for indoor or outdoor use. (Docket No. EERE–2015–BT–STD–0016, DOE, Public Meeting Transcript (December 15, 2015), No. 0060 at pp. 149–150) The Working Group ultimately agreed that an outdoor condensing system must be "capable of maintaining the medium-temperature or low-temperature DOE test procedure box conditions (as specified in 10 CFR 431.304) for an extended period at the 35 °F outdoor temperature condition." (Term Sheet at EERE–2015–BT–STD–0016, No. 0056, Recommendation #1)

DOE considered the Term Sheet's recommendation and is proposing to clarify the recommendation in the context of the walk-in test procedure. First, the recommendation uses the terminology "maintaining the . . . box conditions" in describing an outdoor condensing system. DOE notes that during testing of walk-in refrigeration systems, the space occupied by the unit cooler is conditioned to the specified operating conditions (*e.g.,* 35 °F for medium-temperature systems and −10 °F for low-temperature systems) regardless of the operation of the system being tested. Hence, the test room conditions would not necessarily deviate from these specified temperatures, which would be an indication that the refrigeration system under test is not capable of maintaining the box conditions. DOE proposes that determining whether the refrigeration system can maintain box conditions would be based on the measured net capacity for the system when operating at the 35 °F outdoor condition—specifically, DOE proposes that this net capacity must be no less than 65 percent of the net capacity when tested at 95 °F outdoor conditions for a unit to be considered an outdoor condensing system. DOE selected this comparison because the box loads specified for operation in a 35 °F outdoor condition in AHRI 1250–2009 for outdoor condensing systems during the high load period (Equation 3 for medium-temperature and Equation 7 for low-temperature) are equal to 65 percent of the net capacity measured for the 95 °F outdoor condition.

Second, DOE would clarify that "an extended period" would mean a period of no less than an hour. DOE notes that during testing of walk-in refrigeration systems, AHRI 1250–2009 requires that data be recorded for a period of at least 30 minutes after approaching steady state for at least 30 minutes at the specified test conditions (see section C3.6 in Appendix C of AHRI 1250–2009). Together, the 30 minutes taken to reach steady state and the 30 minutes of data recording time starting after steady state has been achieved add up to an hour of testing. While DOE would expect that an outdoor unit would be able to maintain the required capacity level for many hours, not just one, DOE believes that any inability to maintain this capacity (*e.g.,* due to inability to maintain sufficient refrigerant pressure at the inlet to the expansion device to maintain adequate refrigerant flow) would already have manifested itself within an hour. This is because, for steady-state operation, the refrigerant in a walk-in refrigeration system would circulate through the system many times before an hour would have elapsed,[3] thus if it was going to be "held up" by the expansion valve due to insufficient refrigerant pressure, such an issue would have been observed long before the end of the hour.

Consistent with this approach, DOE is proposing to define an "outdoor dedicated condensing refrigeration system'' as ''a dedicated condensing unit, packaged dedicated system, or matched refrigeration system in which the assembly (including the compressor(s) and condenser) is encased and the system is capable of maintaining a net capacity at the 35 °F outdoor temperature condition that is no less than 65 percent of the net capacity measured at the 95 °F outdoor temperature condition for a period of no less than one hour.''

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[3] For example, for a set of dedicated condensing systems tested by DOE, the range of time required for the refrigerant to circulate fully around the circuit (calculated as the refrigerant charge divided by the mass flow rate) averaged 3 minutes.

Although the Term Sheet originally recommended a definition for ''outdoor condensing unit'' to encompass certain dedicated condensing units and matched condensing units, DOE is proposing a slightly modified definition that expands the scope to packaged dedicated systems (defined in section III.A.1.b). DOE believes its proposed definition is consistent with the intent of the Working Group as expressed in the Term Sheet.

For completeness, DOE is also proposing to define an ''indoor dedicated condensing refrigeration system'' as ''a dedicated condensing refrigeration system that is not an outdoor dedicated refrigeration system.''

DOE requests comments on the proposed definitions for indoor and outdoor condensing units.

e. Unit Cooler

In addition to dedicated condensing systems, the definition of ''refrigeration system'' in 10 CFR 431.302 also includes unit coolers connected to a multiplex condensing system. DOE previously referred to this class of equipment as ''multiplex condensing,'' abbreviated as ''MC.'' However, manufacturers have indicated that unit coolers can be installed in either dedicated condensing or multiplex condensing applications, and that most units that are shipped individually are installed in dedicated condensing systems. (See manufacturer-submitted Excel spreadsheet, Docket No. EERE–2015–BT–STD–0016, No. 0029, noting in column ''K'' that approximately 82 percent of unit coolers are used in dedicated condensing applications, while approximately 18 percent are used in multiplex condensing applications.) In the May 2014 test procedure rule, DOE implemented a certification approach where all unit coolers sold separately (that is, not distributed in commerce as part of a matched-pair system) must be tested and rated as part of the multiplex condensing system class. However, as mentioned in this preamble, these unit coolers could be installed in either dedicated condensing or multiplex condensing applications. The multiplex condensing unit itself is not covered by the standard (as discussed in section III.A.1.a), which could create confusion if the ''multiplex condensing'' reference were to continue to be used. To align its terminology with the actual use of this equipment, DOE is proposing to drop the term ''multiplex condensing'' and re-name this class of equipment as ''unit coolers'' (*i.e.* ''UC'').

In section 3.3 of AHRI 1250–2009, the test procedure incorporated by reference (see 10 CFR 431.303), unit coolers (or, more specifically, ''Forced-Circulation Free-Delivery Unit Coolers (Unit Coolers)'') are defined as ''[a] factory-made assembly, including means for forced air circulation and elements by which heat is transferred from air to refrigerant without any element external to the cooler imposing air resistance. These may also be referred to as Air Coolers, Cooling Units, Air Units or Evaporators.'' DOE believes this definition for ''unit coolers'' is appropriate. However, due to the importance of the term ''unit cooler'' in the walk-in regulations, DOE proposes to add a definition in its test procedure using nearly the same text that currently is used in AHRI 1250–2009. DOE proposes to remove the term ''factory-made'' from the definition to avoid suggesting that such an assembly is not a unit cooler (and thus not covered by DOE regulations) if it happens to be assembled from its subcomponents after shipment from the factory (similar to the approach taken for ''dedicated condensing unit'' as described in section III.A.1.a). Unit coolers would be treated as covered equipment since they would continue to fall within the definition for ''refrigeration system'' as discussed in the next section.

DOE requests comment on its proposal to change the ''multiplex condensing'' class designation to ''unit cooler'' and on its proposal to add a definition for ''unit cooler'' in the CFR, using the definition that currently is in AHRI 1250–2009.

f. Refrigeration System

For purposes of clarity, DOE is proposing to modify the current definition of ''refrigeration system'' in 10 CFR 431.302 to align it with the new definitions discussed earlier. ''Refrigeration system'' is currently defined as ''the mechanism (including all controls and other components integral to the system's operation) used to create the refrigerated environment in the interior of a walk-in cooler or freezer, consisting of: (1) A packaged dedicated system where the unit cooler and condensing unit are integrated into a single piece of equipment; or (2) A split dedicated system with separate unit cooler and condensing unit sections; or (3) A unit cooler that is connected to a multiplex condensing system.'' DOE is proposing to consolidate and re-word clauses (1) and (2) in the current definition to refer to the new, proposed definition for ''dedicated condensing system.'' As the proposed definition for ''dedicated condensing system'' encompasses both packaged dedicated systems and matched refrigeration systems consisting of a dedicated condensing unit and one or more unit coolers, DOE believes the term ''dedicated condensing system'' can replace clauses (1) and (2) in the proposed definition without reducing the overall scope of coverage. This replacement will also serve to clarify that a dedicated condensing unit can also be considered a refrigeration system, as the proposed definition of ''dedicated condensing system'' includes dedicated condensing units.

DOE is also proposing to remove the specification ''that is connected to a multiplex condensing unit'' from clause (3) of the current definition. As discussed in the previous section, walk-in unit coolers can be installed in either dedicated condensing or multiplex condensing applications, and most that are shipped individually are installed in dedicated condensing systems. DOE does not intend to imply that only walk-in unit coolers installed in multiplex condensing applications are covered, because walk-in unit coolers are covered under the standard regardless of whether they are ultimately installed in dedicated condensing or multiplex condensing applications.

The modified definition of ''refrigeration system'' would define this term as ''the mechanism (including all controls and other components integral to the system's operation) used to create the refrigerated environment in the interior of a walk-in cooler or freezer, consisting of: (1) A dedicated condensing refrigeration system (as defined in 10 CFR 431.302); or (2) A unit cooler.''

DOE requests comment on the proposed modifications to the definition of refrigeration system.

g. Adaptive Defrost

The May 2014 test procedure rule implemented a credit for systems having an adaptive defrost system that manufacturers could use in lieu of testing the adaptive defrost feature using the relevant provision in AHRI 1250–2009, incorporated by reference in the DOE test procedure, when calculating the efficiency of their refrigeration systems. (See 10 CFR 431.304(c)(10)(ix)) Manufacturers, however, expressed concerns that DOE had not adequately defined "adaptive defrost" and that the test procedure could permit a manufacturer to claim the energy efficiency credit for systems with this feature even if those systems may not necessarily yield the efficiency performance improvement consistent with the credit provided by the test procedure. (See discussions at Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (September 11, 2015), No. 0061 at p. 0087; and Docket No. EERE–2015–BT–STD–0016, Lennox and Rheem, Public Meeting Transcript (September 30, 2015), No. 0067 at pp. 138–144) To address this issue, DOE offered a definition for "adaptive defrost" for the Working Group to consider during the negotiated rulemaking. In particular, during the October 15, 2015 public meeting, DOE suggested revising the definition for adaptive defrost to refer to a defrost control system that reduces defrost frequency by initiating defrosts or adjusting the number of defrosts per day in response to operating conditions (*e.g.,* moisture levels in the refrigerated space, measurements that represent coil frost load) rather than initiating defrost strictly based on compressor run time or clock time, such that the time interval between defrosts is at least 12 hours when operating in a space maintained at −10 °F and less than 50% relative humidity. (See public meeting presentation, Docket No. EERE–2015–BT–STD–0016, No. 0027 at p. 7)

Commenting on this definition, AHRI, Hussmann, and Lennox questioned whether DOE should specify a time interval between defrosts. Lennox and Hussmann believed that the additional clarification for the time interval was not a necessary part of the definition, while AHRI observed that if adaptive defrost is defined based on a response to moisture levels, the definition should not also indicate defrost frequency because this would effectively make the definition time-based. Hussmann added that a defrost controller may meet the time interval but not function well (a sentiment later reiterated by KeepRite). (Docket No. EERE–2015–BT–STD–0016, AHRI, Hussmann, and Lennox, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 143–145; Keeprite, Public Meeting Transcript (October 15, 2015), No. 0062 at p. 153) Rheem suggested that the adaptive defrost could be dependent on the heat load. (Docket No. EERE–2015–BT–STD–0016, Rheem, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 146) ASAP noted that it was important to verify that an adaptive defrost system is saving energy, but Lennox pointed out that doing so would require the test procedure to be revised to validate the savings of an adaptive defrost system versus a standard defrost approach. ASAP then replied that DOE could specify that the manufacturer is not required to perform the test, but the method could provide a way for DOE to verify performance of the system (Docket No. EERE–2015–BT–STD–0016, ASAP and Lennox, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 146–149) Hussmann then asked whether a mechanism that shortened defrost duration would be considered demand defrost, but DOE noted that the effect of this would be captured during the regular defrost test, and AHRI agreed that reducing the time of the defrost would not be counted under the definition. (Docket No. EERE–2015–BT–STD–0016, Hussmann and AHRI, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 152–156) National Coil suggested that the definition should replace the phrase "response to operating conditions" with "response to frosting conditions," but DOE noted that the definition was not intended to restrict the technology that manufacturers would use to determine when a defrost is necessary. (Docket No. EERE–2015–BT–STD–0016, National Coil, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 159–160) The Working Group was unable to agree on a definition at the time and postponed further discussion until a future meeting.

In the November 3 meeting, several Working Group members and other attendees provided further input on the definition for adaptive defrost. AHRI indicated that the definition should be consistent with the approach followed for heat pumps and require that the unit should sense an actual need for a defrost instead of being based on time. (Docket No. EERE–2015–BT–STD–0016, AHRI, Public Meeting Transcript (December 3, 2015), No. 0057 at p. 131) While AHRI did not specify the type of heat pumps it was referencing, DOE notes that the current test procedure for central air conditioners and heat pumps includes a definition for "demand-defrost control system," which requires the controls to monitor and record at least once for every ten minutes of compressor on-time during space heating one or more parameters that always vary with the amount of frost accumulated (See 10 CFR 430, subpart B, appendix M, sec. 1). Emerson raised the issue of how to assign an adaptive defrost credit if the unit cooler and condensing unit were sold separately and argued that the definition should cover the case where the sensors and communication board are on the unit cooler and the system's processing power (*i.e.,* decision-making) is located on the condensing unit. Lennox and AHRI agreed that it would not be necessary for both components to have all of the necessary features for the system as a whole to have adaptive defrost capability, and Hussmann noted that some systems have all of the necessary components on the unit cooler. Emerson and Rheem then questioned how the condensing unit could receive credit for the system having adaptive defrost ability in this case, when the manufacturer would not know whether it was going to be paired with a unit cooler that has the capability for using adaptive defrost. Rheem noted that, in this situation, any components that the manufacturer included on the condensing unit would ultimately be unused. (Docket No. EERE–2015–BT–STD–0016, AHRI, Lennox, Emerson, Rheem, and Hussmann, Public Meeting Transcript (December 3, 2015), No. 0057 at pp. 132–140) Hussmann then suggested that the manufacturer of the condensing unit could show that the unit has adaptive defrost compatibility with a note in the instruction manual or a sticker on the unit, but ASAP expressed concern that the condensing unit could, in spite of the instructions, be installed with a unit cooler that does not have adaptive defrost capability. (Docket No. EERE–2015–BT–STD–0016, Hussmann and ASAP, Public Meeting Transcript (December 3, 2015), No. 0057 at pp. 142–144)

As discussed in section III.A.2.b, the Working Group agreed, and DOE is separately proposing, that manufacturers should rate their systems for compliance purposes without the adaptive defrost credit, but that the test procedure would continue to retain its current method for calculating the benefit of adaptive defrost to permit manufacturers to make representations of system efficiency with this feature included. After settling on this approach, the Working Group agreed on a definition of adaptive defrost without resolving the question of how DOE would verify that a unit cooler or condensing unit has adaptive defrost capability. Consistent with the Term Sheet, DOE proposes to define "adaptive defrost" as "a defrost control system that reduces defrost frequency by initiating defrosts or adjusting the number of defrosts per day in response to operating conditions (*e.g.,* moisture levels in the refrigerated space, measurements that represent coil frost load) rather than initiating defrost strictly based on compressor run time or clock time." See Docket No. EERE–2015–BT–STD–0016, Public Meeting Transcript (December 15, 2015), No. 0060 at p.157.

The proposed definition does not specify which features must be included on (or with) the unit cooler or condensing unit; based on the discussion outlined in this preamble, features may not be consistent across manufacturers or installed systems. Also in accordance with Working Group recommendations discussed earlier in this section, the proposed definition specifies that the defrost is initiated based on operating conditions and not on time. Although the proposed definition lists some examples of operating conditions, it does not prescribe which conditions the controller must rely on to initiate the defrost.

DOE requests comment on the proposed definition for adaptive defrost.

h. Process Cooling, Preparation Room Refrigeration, and Storage Space

The statutory definition of a walk-in cooler is "an enclosed storage space refrigerated to temperatures, respectively, above, and at or below 32 degrees Fahrenheit that can be walked into, and has a total chilled storage area of less than 3,000 square feet; however, the terms do not include products designed and marketed exclusively for medical, scientific, or research purposes." (42 U.S.C. 6311(20)) The use of the term "storage space" in the definition raises questions about which refrigerated spaces would qualify as a "storage space" and thereby comprise equipment subject to the walk-in standards.

To address this ambiguity, Working Group meeting participants asked DOE to add definitions to help clarify certain refrigeration system applications. (See manufacturer-submitted material at Docket No. EERE–2015–BT–STD–0016, No. 0006 at p. 2 and Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (August 27, 2015), No. 0015 at pp. 96–97; and Docket No. EERE–2015–BT–STD–0016, AHRI, Public Meeting Transcript (December 15, 2015), No. 0060 at pp. 141–142) As part of the negotiated terms, DOE agreed to create walk-in-specific definitions for "process cooling," "preparation room refrigeration," and "storage space." (See Term Sheet at EERE–2015–BT–STD–0016, No. 0056, Recommendation #7) In the following paragraphs, DOE discusses its proposed definitions for these terms.

Process Cooling

Interested parties first asked DOE to clarify the applicability of standards to certain types of process cooling refrigeration systems during the initial rulemaking that culminated in the June 2014 final rule. In the preamble to that final rule, DOE clarified that blast chillers and blast freezers (which it considered types of process cooling) would not be required to meet the walk-in standards. At the time, DOE explained its understanding that the description contained in that document was sufficiently clear to enable manufacturers to readily determine whether a particular device they produce would be subject to the standards. DOE further noted that equipment used solely for process cooling applications is generally excluded from the standards, but that it could not categorically exclude from coverage any products used for both process and storage applications. 79 FR at 32068.

At a subsequent public meeting that DOE held in October 2014 to clarify aspects of the test procedure, DOE again stated that blast chillers and blast freezers did not fall within the scope of the energy conservation standards established for walk-ins in the June 2014 final rule. However, DOE acknowledged at the time that it did not have a definition for "process" cooling in the context of walk-ins. (Docket No. EERE–2011–BT–TP–0024, Heatcraft and DOE, Public Meeting Transcript (October 22, 2014), No. 0117 at pp. 61–63)

DOE has considered process cooling more carefully in light of the Working Group's request to develop clarifying definitions. DOE concludes that its initial statements in the 2014 final rule that blast chillers and blast freezers are not walk-ins were in error. DOE now believes that these categories of equipment, referred to as "process cooling equipment" do fall under the EPCA definition for walk-ins and are, for the reasons that follow, subject to standards. DOE notes that it is proposing an approach for process cooling equipment that differs from the component-based approach that applies to other walk-ins.

In again reviewing DOE's treatment of process cooling, DOE first considered whether process cooling equipment that resembles walk-ins are indeed walk-ins as defined by EPCA. DOE has tentatively determined that certain equipment marketed as blast chillers and/or blast freezers (and discussed in the context of this rulemaking as process cooling equipment (see, *e.g.*, 79 FR at 36067 (June 3, 2014)) meet the requirements for walk-in coolers and freezers under the EPCA definition. EPCA defines "walk-in" as an "enclosed storage space." (42 U.S.C. 6311(20)(A)) However, the statute does not define "storage" and provides no minimum duration for a stored item to remain within the walk-in to qualify as storage. As noted earlier, the Working Group asked DOE to develop a definition for "storage space," which indicates that there is not necessarily a clear distinction between storage space and process space in the context of walk-in coolers and walk-in freezers.

In applying the statute's use of the term "storage space," the key question is whether the use of a blast chiller's refrigerated space for rapid pulldown of the temperature of the contents placed within the enclosure, in and of itself, excludes the internal space from being considered storage space. On one hand, the contents are being acted upon rather than simply passively sitting. On the other hand, these contents are also placed in the space for a certain period of time, *i.e.*, the contents are placed in the space for later access. In the June 2014 final rule, DOE referenced a period of 90 minutes when discussing the difference between process equipment and walk-ins. See 79 FR at 32068. DOE considered whether the referenced time period is appropriate to distinguish between a storage and process cooling application. DOE has tentatively determined, however, that the duration of time that contents are stored in the equipment is not an appropriate means for excluding certain equipment from the definition of walk-in cooler or walk-in freezer because there is no clear standard demarcating a boundary between what does and does not constitute storage. To the extent that this equipment is an enclosed refrigerated space that can be used to retain goods for an unspecified period of time and can be walked into with a chilled area less than 3,000 square feet and is not designed and marketed exclusively for medical, scientific, or research purposes, even if the goods are being interacted with/upon while in the chilled area (see 42 U.S.C. 6311(20)), DOE now considers this equipment to be a walk-in. Hence, DOE is clarifying that process cooling equipment, including blast chillers and blast freezers, fall within the statutory definition for walk-in coolers and freezers.

In light of this clarification of how process-cooling applications fit within the EPCA definition of WICF, DOE also reviewed the applicability of the statutory standards for the three primary walk-in components. Currently, panels, doors, and refrigeration systems must meet statutorily prescribed standards as set forth in 42 U.S.C. 6313(f) (codified at 10 CFR 431.306(a)–(b)). These statutorily prescribed standards apply to all regulated walk-in components used in any equipment that meets the definition of a WICF regardless of its end-use application—subject to the exceptions already noted in the definition. Consequently, DOE is also clarifying in this rulemaking that WICF panels, doors, and refrigeration systems used in process cooling applications are subject to the statutory design standards and these components must be certified as compliant with the applicable WICF component-based standard.

Since DOE previously erred in indicating that WICFs used exclusively for process-cooling such as blast chilling and freezing are not subject to walk-in regulations, DOE recognizes that manufacturers may require time to comply with the statutorily prescribed walk-in requirements. Consequently, WICF components used in process-cooling WICFs and process-cooling WICFs manufactured prior to the final rule would not be held to the statutory standards. Further, DOE will exercise its enforcement discretion for 60 days after publication of the final rule, to allow manufacturers of WICF components that are used exclusively in process cooling applications to comply and to certify compliance with the applicable statutory standard. DOE believes that WICF panels and doors would already comply with the statutorily prescribed standards because there are no door or panel designs exclusively associated with process cooling equipment. Accordingly, none of these components would have been impacted by DOE's prior views regarding process cooling equipment. However, DOE understands that refrigeration systems used in process cooling equipment such as blast chilling and freezers have a specific set of operating requirements that could require some level of redesign to enable them to comply with the statutorily prescribed standards. DOE seeks comment on the enforcement discretion timeframe from manufacturers of WICF refrigeration systems used in process cooling applications including any associated rationale about the level of redesign needed to comply with the EPCA standards.

In addition, DOE adopted a component-based regulatory approach for walk-ins when it evaluated amended energy conservation standards for WICFs in the July 2014 final rule. Rather than developing standards applicable to the entire walk-in cooler or freezer, DOE established performance-based standards for components, including panels, doors, and refrigeration systems. As part of this clarification, DOE considered whether these component-level standards apply to process cooling equipment.

As noted in this preamble, DOE does not consider the panels and doors of process refrigeration walk-ins to be unique from those of other walk-ins. DOE is unaware of any differences between the doors and panels used with standard walk-ins and those walk-ins used with process cooling applications, and the analysis for these components supporting the June 2014 final rule standards included all such panels and doors without regard to the application in which they were installed. Furthermore, DOE has no information suggesting performance requirements for these groups of equipment differ from each other based on application. Specifically, the rapid temperature pull-down associated with process equipment does not impose performance requirements on the panels and doors that are any different than the requirements for panels and doors of other walk-ins. Consequently, DOE considers the efficiency performance standards for doors established in the 2014 final rule to apply to WICFs used in process refrigeration applications.

However, DOE recognizes that process cooling refrigeration systems can be distinct from the refrigeration systems of other walk-ins. Specifically, process cooling refrigeration systems must be able to rapidly cool down and/or freeze the contents of a process cooling walk-in. In order to achieve rapid cooldown, process cooling WICF refrigeration systems have unique characteristics such as a higher refrigeration capacity on a per volume basis and unit cooler designs that extend nearly the full height of the WICF allowing the discharge air to directly impinge on the product being cooled to enhance heat transfer. The temperature change demanded of process cooling refrigeration systems must be accomplished within a certain amount of time that is governed by restraints such as health regulations that require rapid cool-down of cooked food. This rate of cool-down typically cannot be achieved by the types of walk-in refrigeration systems addressed by DOE's rulemakings to date. Consequently, DOE expects that at least some process cooling refrigeration systems would be unable to meet the walk-in standards, which are based on the performance of refrigeration systems designed for storage applications requiring that a specific temperature level be maintained. The characteristics of this process cooling equipment and the basis for the proposed "process cooling" definition is discussed in greater detail in the discussion that follows. DOE views equipment meeting this definition as exempt from the walk-in refrigeration system standards—both those established in the June 2014 final rule and those that DOE is proposing as part of a separate rulemaking to address the vacated standards mentioned elsewhere in this document.

Blast chillers and blast freezers are examples of process cooling WICFs. Although there are other types of refrigeration that could be considered process cooling—for example, spiral chillers and freezers (where food is moved on a conveyor belt in a spiral around a central multi-directional cooling unit)—these other types are unlikely to be mistaken for a refrigeration system that would be subject to the walk-in standards because of clear and observable differences in physical configuration, for this example, the spiral conveyor for the food products of a spiral freezer resembles none of the subcomponents of other walk-ins. On the other hand, blast chillers and blast freezers superficially resemble other walk-ins in outside appearance and physical size—factors that make it plausible that these equipment might, without clarification from DOE, be considered as covered by the walk-in standards. Thus, DOE attempted to identify characteristics of blast chillers and blast freezers that would clearly distinguish them from other walk-ins that must meet the applicable refrigeration system standards.

One clear distinguishing characteristic is that the refrigeration system capacity of a blast chiller or freezer is much higher relative to the internal volume of the enclosure as compared to other typical walk-ins. This is because the refrigeration load includes the large load associated with the required rapid cool-down of the product. In situations where the refrigeration system is distributed in commerce with the rest of the blast chiller or freezer components, it is easy to distinguish the refrigeration system from those of other typical walk-ins on the basis of capacity versus cabinet size, because, for this situation, both the capacity and the cabinet size would be known. Therefore, DOE's proposed definition for process cooling includes a minimum ratio of capacity versus cabinet size in cases where the refrigeration system is distributed in commerce with the cabinet.

However, in cases where the refrigeration system is distributed separately and, consequently, the cabinet size may not be known, this definition would be insufficient. Hence, the ideal definition would also include a way to determine whether the process cooling refrigeration system *on its own* is distinct from those of other typical walk-ins that are shipped without their associated enclosures. DOE researched blast chiller and freezer data and found that when evaluated independently of the cabinet size, refrigeration capacities for certain blast chillers and freezers fall within the range of capacities of other walk-in refrigeration systems. Thus, it does not appear that process cooling refrigeration systems can be distinguished based on refrigeration capacity alone in cases where the refrigeration system is distributed separately from the enclosure.

For this reason, DOE also identified physical characteristics of blast chiller and blast freezer refrigeration systems that would distinguish them from other refrigeration systems. First, some blast chiller and freezer refrigeration systems consist of separate coil and fan assemblies, with the coil and the fan placed during installation on opposite sides of the enclosure to more evenly distribute the airflow. These types of systems would be excluded from the standards because the equipment would not meet the proposed definition of a unit cooler—that is, a single assembly that includes the fan(s) and coil(s). See section III.A.1.e regarding DOE's proposed "unit cooler" definition. Second, for those blast chiller and freezer refrigeration systems for which a single factory-assembled unit houses the fans and evaporator coil, these systems are also distinct from unit coolers subject to the walk-in standards in that they have a height that nearly fills the vertical dimension of the insulated enclosure and have fans that are stacked on top of each other to blow air directly onto the items being chilled or frozen. In comparison, unit coolers used in other walk-ins have a limited vertical dimension and have fans oriented side-by-side in the direction of the unit's width (or have only one fan). These unit coolers are also generally installed so that they blow air over the top of the stored items—the height of this space in a walk-in may not be very high (in order to maximize use of the available space)—hence, the unit coolers and their fans are oriented horizontally instead of vertically. Consistent with these findings, the proposed process cooling refrigeration definition incorporates a qualifier on the physical dimensions of the unit cooler.[4]

DOE notes that the physical distinctions it found apply only to the unit cooler and not to the condensing unit. DOE has found no evidence that condensing units used with blast chillers and freezers are materially different from those used with other refrigerated enclosures or that these condensing units have features that would make them unable to meet a walk-in standard for dedicated condensers.

For the reasons outlined in this preamble, DOE proposes to define "walk-in process cooling refrigeration system" as "a refrigeration system that is used exclusively for cooling food or other substances from one temperature to another. A process cooling refrigeration system must either (1) be distributed in commerce with an enclosure consisting of panels and door(s) such that the assembled product has a refrigerating capacity of at least 100 Btu/h per cubic foot of enclosed internal volume, or (2) be a unit cooler having an evaporator coil that is at least four-and-one-half (4.5) feet in height and whose height is at least one-and-one-half (1.5) times the width." This proposed definition would cover both process cooling systems that are distributed in commerce as part of a complete assembly, process cooling unit coolers that are distributed separately from the enclosure, and refrigeration systems including unit coolers meeting the process cooling definition.

These exclusions would apply to (a) refrigeration systems sold as part of a complete package, including the insulated enclosure, and the refrigeration system for which the capacity per volume meets the proposed process cooling definition, (b) dedicated condensing systems sold as a matched pair in which the unit cooler meets the requirements of the proposed process cooling definition, and (c) unit coolers that meet the requirements of the proposed definition. DOE intends to propose specific regulatory language expressing these exclusions as part of its concurrent energy conservation standards rulemaking. However, because having a clear way to differentiate process cooling equipment from other walk-ins is essential to ensure clarity for manufacturers with regard to whether the equipment it manufactures would need to satisfy an applicable energy conservation standard, DOE seeks comment on the proposed definition and any additional information that would help to delineate this equipment more clearly.

DOE does not intend for the proposed process cooling definition to have the effect of excluding process cooling refrigeration from the definition of a walk-in cooler or freezer. Process cooling refrigeration systems would remain subject to other walk-in-related regulations, such as the labeling requirements discussed in section III.B.5 that DOE is considering, along with the prescriptive requirements for walk-ins already prescribed by Congress in EPCA. See 42 U.S.C. 6313(f). A complete process cooler would also need to be assembled using panels and doors that comply with the applicable requirements. See 42 U.S.C. 6313(f) and 10 CFR 431.306. DOE may also examine the possibility of regulating the energy efficiency of process cooling refrigeration systems at a later date, but consideration of such regulation would also include consideration of alternative test procedures and/or equipment classes to address the different operating and energy use characteristics of this equipment.

DOE requests comment on the definition for process cooling refrigeration system. DOE also requests data or information on any other qualities, characteristics, or features *specific to the refrigeration system itself* (either mentioned in this section or not) that would clearly distinguish process refrigeration from other refrigeration systems or would cause a certain process refrigeration system to be unable to meet a walk-in refrigeration system standard. DOE particularly requests data for condensing units distributed individually; in the absence of any evidence that individual condensing units designed for process refrigeration are fundamentally different from other individual condensing units, DOE will have no basis for excluding such condensing units from the scope of the standards. Further, DOE requests comment on the proposal to allow 60 days after publication of the final rule for manufacturers of process cooling refrigeration systems to attain compliance with the applicable regulations.

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[4] DOE is not proposing to distinguish process cooling refrigeration systems on the basis of evaporator fan power, evaporator air velocity, or evaporator air flow, which are generally higher for these systems as compared with unit coolers used predominately in other walk-ins. Evaporator fan power, velocity, or air flow of a unit cooler could be atypically high for a number of reasons, including the use of inefficient fans or motors, long air "throw" distance, and other factors. Consequently, an approach based on the evaporator's fan power, air velocity, or air flow alone would be inadequate to consistently distinguish process cooling from other refrigeration systems.

Preparation Room Refrigeration

During the public meeting that DOE held in October 2014 to clarify aspects of the test procedure, Heatcraft, a refrigeration system manufacturer, asked whether preparation rooms are also excluded from the definition of walk-ins. DOE could not at the time determine whether refrigeration systems designed for this application should be categorically excluded. (Docket No. EERE–2011–BT–TP–0024, Heatcraft, Public Meeting Transcript (October 22, 2014), No. 0117 at pp. 61–63)

DOE further investigated this refrigeration application as part of its effort to define "preparation room refrigeration" in accordance with the Term Sheet. Commercial and industrial food sales and food service establishments often prepare food (primarily meat) in spaces that are refrigerated and can be walked into, making the distinction between these spaces and walk-ins unclear. Similar to the process refrigeration definition discussed earlier, DOE sought to identify characteristics of preparation room refrigeration equipment that would distinguish it from walk-in refrigeration equipment. An engineering manual published by Heatcraft notes that preparation room refrigeration loads are sized to account for personnel and processing equipment; the evaporator "should be [a] low outlet velocity type to avoid drafts and should be selected for continuous operation and not less than 30 °F evaporator temperature." (Docket No. EERE–2016–BT–TP–0030, No. 0001 at p. 19) A manufacturer had also commented during the previous rulemaking (ending in the June 2014 final rule) that meat processing rooms in particular have electric or hot gas defrost even when they are designed for room temperatures above 32 degrees Fahrenheit. (Docket No. EERE–2008–BT–STD–0015, Hussmann, No. 0093 at p. 9)

Based on these characteristics, DOE is proposing to define "preparation room refrigeration" as referring to "a unit cooler that is designed for use in a room occupied by personnel who are preparing food and that is characterized by low outlet air velocity, evaporator temperature between 30 and 55 degrees Fahrenheit, and electric or hot gas defrost."

While DOE is proposing to define this type of refrigeration system, this equipment would not be exempt from the applicable standards under this proposal. Some of the system's characteristics, such as low air velocity and a relatively high evaporating temperature, do not clearly distinguish this type of refrigeration from other types used in walk-ins subject to standards. Furthermore, DOE has not found evidence that this refrigeration system would have undue difficulty meeting a standard when rated using the DOE test procedure. Although these units may have electric or gas defrost, their operating temperature would place them in the medium-temperature class, and the test procedure (both the current test procedure and the test procedure as proposed in this notice) adds no energy use associated with defrost for medium-temperature systems. Thus, the defrost energy would not be measured under the test procedure and not be factored into the unit's rating.

DOE requests comment on the proposed definition for preparation room refrigeration. DOE requests comment on any other characteristics of preparation room refrigeration that (1) clearly distinguishes it from walk-in refrigeration systems *and* (2) would cause this equipment to be unable to meet a walk-in refrigeration standard.

Storage Space

Finally, consistent with the Term Sheet, DOE is proposing to define "refrigerated storage space" in the context of the current definition for a walk-in as follows: The term "refrigerated storage space" would be defined to mean "a space held at refrigerated (as defined in 10 CFR 431.302) temperatures." DOE is aware that this definition does not delineate a difference between equipment that is subject to standards and equipment that is not subject to standards, but believes that the previous discussions on process refrigeration and preparation room refrigeration sufficiently indicate what types of equipment are or are not subject to standards.

DOE requests comment on the proposed definition for "refrigerated storage space." DOE requests comment on whether any further clarification is needed to clearly distinguish equipment that is subject to the standard from equipment that is not.

2. Refrigeration System Test Procedure Modifications

a. Hot Gas Defrost

DOE proposes to amend the current test procedure by removing the method for calculating the defrost energy and heat load of a system with hot gas defrost. The May 2014 test procedure rule established a calculation to represent the efficiency improvement of hot gas defrost as a credit applied to any low-temperature refrigeration system that has the feature. The amended test procedure did not include a test method for validating the performance of this feature. Instead, the method applied standardized values for the energy use and heat load associated with hot gas defrost in the calculations to determine AWEF. See 79 FR at 27400 (May 13, 2014). During the first Working Group meeting, Lennox (representing a caucus of manufacturers) requested that DOE remove hot gas defrost as a design option in the energy conservation standard analysis for a number of reasons, including (a) the lack of any method for measuring the true energy benefit of this feature, (b) the lack of test data and research supporting the energy credit in the DOE test procedure, (c) installation and serviceability issues such as an increase in refrigerant leaks, and (d) energy penalties for hot gas defrost in installed systems that would not be captured in the test procedure credit. (Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (August 27, 2015), No. 0015 at pp. 94–95; see also manufacturer-submitted material at Docket No. EERE–2015–BT–STD–0016, Working Group Meeting Materials, No. 0006 at p. 1) In a subsequent meeting, other members of the Working Group again noted that there was a lack of data to support the credit. (Docket No. EERE–2015–BT–STD–0016, Rheem, Public Meeting Transcript (September 11, 2015), No. 0061 at p. 40–41 and Lennox, id. at pp. 44–46) Hussmann also claimed that DOE's assigned value of zero energy use for hot gas defrost in multiplex condensing systems was not correct because hot gas defrost would affect the system's energy efficiency ratio ("EER"). Hussmann noted that the EER in the test procedure is based on a system with electric defrost, but systems with hot gas defrost may experience a reduction in the overall system efficiency.[5] (Docket No. EERE–2015–BT–STD–0016, Hussmann, Public Meeting Transcript (September 11, 2015), No. 0061 at p. 42) (See also manufacturer-submitted comments (Docket No. EERE–2015–BT–STD–0016, No. 0008 at pp. 15–17))

At the September 30, 2015 Working Group meeting, DOE presented test data and additional analysis in response to Working Group member concerns. The data and analysis showed that the credit for hot gas defrost in the test procedure is consistent with the measured benefit for a condensing unit operating in an ambient air temperature of 90 °F. (Docket No. EERE–2015–BT–STD–0016, Public Meeting Presentation (September 30, 2015), No. 0007 at pp. 10–17) However, Rheem observed that this credit-based approach may not reflect annual average impact, because hot gas defrost performance is affected by outdoor temperature. (Docket No. EERE–2015–BT–STD–0016, Rheem, Public Meeting Transcript (September 30, 2015), No. 0067 at pp. 76 and 81) Hussmann added that many hot gas defrost systems incorporated in single-compressor dedicated condensing refrigeration systems do not work properly at ambient temperatures below 40 °F. (Docket No. EERE–2015–BT–STD–0016, Hussmann, Public Meeting Transcript (September 30, 2015), No. 0067 at p. 83) Rheem also pointed out that some unit coolers use both hot gas and electric defrost and that the test procedure's credit does not distinguish between hot gas defrost systems that provide pan heating using electric heaters from those systems that provide hot gas pan heating. The credit as applied assumes that there is no electric heating, but Rheem noted that in many applications the drain pan has electric defrost even if the rest of the system uses hot gas defrost. (Docket No. EERE–2015–BT–STD–0016, Rheem, Public Meeting Transcript (September 30, 2015), No. 0067 at pp. 90–91) DOE notes that the amended test procedure from the May 2014 test procedure rule did not define hot gas defrost or provide an indication of what percentage of defrost heat must be provided by hot gas defrost for a system to be eligible for the credit. See 79 FR 27388. Lennox further recommended that DOE's engineering analysis should account for a 2-psi suction line pressure drop to account for the presence of the reversing valve that is used in many hot gas defrost systems to enable use of the feature. (Docket No. EERE–2015–BT–STD–0016, Lennox, Public Meeting Transcript (September 30, 2015), No. 0067 at p. 90)

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[5] Depending on how hot gas defrost is implemented in a multiplex system, there are a number of factors which could cause additional energy use in the system and/or increase head pressure, which would reduce the EER of the system and therefore indirectly increase the overall system energy use.

DOE revised its analysis to address these Working Group comments. Specifically, DOE implemented changes to the engineering analysis, including accounting for the reversing valve pressure drop, effects on the EER of a multiplex condensing system associated with an increase in head pressure, and an adjustment of cost assumptions. DOE presented these analysis updates in the following public meeting. (Docket No. EERE–2015–BT–STD–0016, DOE, Public Meeting Presentation (October 15, 2015), No. 0026 at pp. 31–39; see also Docket No. EERE–2015–BT–STD–0016, various parties, Public Meeting Transcript (October 15, 2015), No. 0062 at pp. 215–226)

As part of the negotiated terms, DOE agreed to remove the calculation method for determining the benefit of hot gas defrost from the test procedure. See Term Sheet at EERE–2015–BT–STD–0016, No. 56, recommendation #3. The regulatory text in this proposed rule reflects this change. With this change, manufacturers of refrigeration systems with hot gas defrost will be unable to test or rate the performance of the feature with the DOE test procedure. Therefore, in a separate rulemaking in which DOE is proposing standard levels for walk-in refrigeration systems, DOE is not evaluating hot gas defrost as an option for manufacturers to meet the proposed standards. Nevertheless, DOE continues to believe that hot gas defrost systems can reduce energy use and that their inclusion as part of an accepted test method to report their energy efficiency impact would benefit the public by illustrating these systems' energy savings potential. DOE encourages interested parties to consider development of such test methods for potential future inclusion into DOE's test procedures.

DOE requests comments on its proposal to remove from the test procedure the credit-based method for calculating the efficiency benefit of hot gas defrost.

b. Adaptive Defrost

Consistent with the recommendations made during the Working Group negotiations, DOE is proposing to amend the test procedure so that the provisions for assigning a benefit to adaptive defrost cannot be used to certify compliance with the energy conservation standard. AHRI 1250–2009, the test procedure incorporated by reference, includes an optional test for a system with adaptive or demand defrost. That test specifies that the system shall be operated at dry coil conditions to establish the maximum time interval allowed between dry coil defrosts. The measured time between dry coil defrosts is averaged with the time between defrosts under the frosted coil conditions, and this average is used as the number of defrosts per day in subsequent energy calculations. (See appendix C, section C11.2 of AHRI 1250–2009.) DOE's May 2014 test procedure final rule further allowed that in lieu of conducting the optional test, the number of defrosts per day is set to the average of 1 and the number of defrosts per day is calculated under the frost load conditions. (10 CFR 431.304(c)(10)(x)) The May 2014 test procedure rule also specified that if defrost testing at frost load conditions is not conducted, the energy use of defrost under frost load conditions shall be set to a percentage of the energy use of defrost under dry coil conditions, and the number of defrosts per day under the frost load conditions shall be set to 4. (10 CFR 431.304(c)(10)(ix)) Thus, if a manufacturer were to use the default values in the test procedure in lieu of testing a system with adaptive defrost, the total number of defrosts per day would be 2.5—the average of 1 and 4. Similar to hot gas defrost, the current test procedure does not require performance verification of adaptive defrost to obtain the credit.

Given the number of possible ways manufacturers could implement adaptive defrost, Working Group meeting participants suggested that DOE clearly define this term to specify which types of systems would be allowed to obtain the credit in the test procedure, and to avoid loopholes in which a manufacturer might claim the benefit for a given system with minimal cost impact but that would not have the associated savings realized in the field. As discussed in section III.A.1.g, several Working Group members and other attendees—AHRI, Emerson, Lennox, Hussmann, McHugh Energy, HTPG, and ASAP—provided input on a possible definition, but remained concerned that the definition would still not adequately define this feature in a way to ensure that all systems meeting the definition would produce an efficiency improvement consistent with the test procedure credit. (Docket No. EERE–2015–BT–STD–0016, various parties, Public Meeting Transcript for December 3, 2015 Meeting, No. 0057 at pp. 130–153) Ultimately, DOE suggested that certified ratings and standards should be based on equipment not having the feature, although the test procedure could still include a rating method to allow manufacturers to make representations regarding improved performance for equipment having the feature. (Id.) The Term Sheet included a definition for adaptive defrost (see supra, section III.A.1.g), but also specified that manufacturers should be required to certify compliance to DOE for walk-in refrigeration basic models without adaptive defrost, and that compliance with the applicable walk-in refrigeration system standard should be assessed based on systems without adaptive defrost. The Term Sheet also recommended that manufacturers be permitted to make representations of the energy efficiency or consumption for a basic model using adaptive defrost, provided that the improved efficiency for this basic model is also certified to DOE. See Term Sheet at EERE–2015–BT–STD–0016, No. 0056, Recommendations #2 and #4.

c. On-Cycle Variable-Speed Evaporator Fan Control

As noted in section III.A.1.e, the majority of unit coolers that would be rated individually (*i.e.,* as though they were paired with multiplex condensing systems) are, in fact, installed in dedicated condensing applications, and most dedicated condensing applications are single-capacity systems. On-cycle variable-speed evaporator fans as a design option would save energy only when they are part of a multi- or variable-capacity system. This option would improve the measured efficiency of a stand-alone unit cooler using the current test procedure, which is conducted for stand-alone unit coolers as if they were used in multiplex applications. However, the savings predicted for this design option by the test procedure would not be achieved in the majority of field installations, which use single-stage dedicated condensing units. Accordingly, manufacturers in the Working Group objected to including in the analysis design options that would not be useful to the majority of end-users. (Docket No. EERE–2015–BT–STD–0016, No. 0006 at p. 1 and Docket No. EERE–2015–BT–STD–0016, various parties, Public Meeting Transcript for September 11, 2015 Meeting, No. 0061 at pp. 56–72)

The Working Group ultimately recommended that manufacturers be required to make representations, including certifications of compliance to DOE, of the energy efficiency or energy consumption of walk-in refrigeration systems without the inclusion of on-cycle variable-speed fans. See Term Sheet at EERE–2015–BT–STD–0016, No. 0056, Recommendation #4. Likewise, they recommended that compliance with the applicable walk-in refrigeration system standard should be assessed without using this feature. As part of this approach, manufacturers would be permitted to make representations of the energy efficiency or consumption for a unit cooler basic model using on-cycle variable-speed fans as measured in accordance with the DOE test procedure, provided that the additional represented value has been certified to DOE per 10 CFR 429.12. Id. However, the benefit from using these technologies would not be factored when determining compliance with the proposed standard. Id. DOE is proposing to adopt these changes to the test procedure.[6]

B. Actions To Facilitate Implementation of Energy Conservation Standards

1. Re-organization and Clarification of the Test Procedure for Walk-In Refrigeration Systems, Doors, and Panels

Other than the test procedure changes proposed in section III.A.2, DOE is also proposing to amend the regulatory text to clarify the test procedure for refrigeration systems, doors, and panels. The proposed changes focus on re-organizing the test procedure into three separate appendices, one for each of the metrics used to establish energy conservation standards for walk-in components. In addition, DOE proposes to clarify some of the definitions and terminology used in the test procedure.

Currently, Appendix A to Subpart R of Part 431 contains the procedure for measuring energy consumption (in kWh/day) for display and non-display doors. DOE proposes to revise Appendix A to remove definitions and references related to walk-in panels, as these are not relevant to this procedure. Specifically, DOE proposes to remove (1) the definitions of "core region" and "edge region" and (2) the subfloor temperature listed in Table A.1 of Appendix A. DOE proposes to amend the definition of "surface area" to remove the example referencing walk-in panels and amend the definition of "rating condition" to remove the discussion of internal walk-in components. These amendments are intended to clarify Appendix A and do not substantively change the DOE test procedure for measuring energy consumption of walk-in doors.

To address questions from the Working Group regarding how to calculate door power usage, DOE proposes to define "rated power," a term used in section 4.4.2(b) and 4.5.2(b) of Appendix A to Subpart R to Part 431. In the January 4, 2010 test procedure NOPR for walk-ins, DOE explained that the term "rated power" must be read from each electricity consuming device's product data sheet or nameplate. 75 FR 186, 199. Consistent with this prior explanation, and to address scenarios where nameplate information is unavailable, DOE is proposing to define this term as referring to "the electricity consuming device's power as specified on the device's nameplate. If the device does not have a nameplate or such nameplate does not list the device's power, then the rated power must be read from the device's product data sheet."

For each basic model of walk-in door that has an electricity consuming device(s) for which rated power is taken from a product data sheet, the walk-in door manufacturer must retain the product data sheet as part of the test data underlying the walk-in door's certification report.

To further clarify the walk-in test procedure, DOE proposes to add a new Appendix B to Subpart R of Part 431. This appendix would include the currently prescribed method of measuring the R-value found in 10 CFR 431.304. Specifically, DOE proposes to move the provisions found at 10 CFR 431.304(b) and (c) into Appendix B. DOE also proposes to add the definition of "edge region" that was previously located in Appendix A to Subpart R of Part 431 to Appendix B, as this definition is relevant to the R-value test method.

Finally, DOE proposes to add a new Appendix C to Subpart R of Part 431 and include in this appendix the test method for refrigeration systems. Within Appendix C, DOE further organizes its discussion of test procedures in terms of the three refrigeration system configuration types that it addresses: Refrigeration systems distributed in commerce as matched pairs (including packaged dedicated systems); unit coolers distributed in commerce individually; and condensing units distributed in commerce individually. Within Appendix C, DOE is specifying that walk-in refrigeration systems be tested using AHRI 1250–2009, the test procedure incorporated by reference in 10 CFR 431.303, and adding modifications to the rule. One subsection contains the general modifications to the test conditions and tolerances within the industry test procedure that were promulgated in the May 2014 test procedure rule, a second contains general modifications to the method of test, while the remaining subsections address modifications that are specific to the system configuration types.

DOE is also proposing to correct a small number of typographical errors in the regulatory text. A table currently in 10 CFR 431.304(c)(10)(xv), replacing Table 16 in AHRI 1250–2009, has incorrect values for saturated suction temperature. The suction A and suction B temperatures should be −20 °F and −26 °F, respectively. Also, an equation currently in 10 CFR 431.304(c)(12)(ii) for defrost heat load contribution divides by 3.412 Btu/W-h, but should multiply by 3.412 Btu/W-h.

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[6] DOE notes that it did not consider these technologies in its supporting analysis regarding the dedicated condensing (low-temperature) and multiplex condensing refrigeration system standards that it is planning to propose separately.

2. Representation Requirements

DOE is proposing to amend the representation requirements for refrigeration systems to clarify how to apply the test procedure to the range of possible kinds of refrigeration systems. Specifically, DOE is proposing to direct manufacturers of unit coolers, dedicated condensing units, package dedicated systems, and matched refrigeration systems to the appropriate subsections of Appendix C to Subpart R of Part 431—the DOE test procedure for refrigeration systems. DOE is also proposing to specify that it is not necessary to rate a matched refrigeration system if the constituent unit cooler(s) and dedicated condensing unit have been tested and rated separately. However, if a manufacturer wishes to represent the efficiency of the matched refrigeration system as distinct from the efficiency of either constituent component, or if the manufacturer cannot rate one or both of the constituent components using the specified method (*e.g.,* if the system has a variable-capacity condensing unit, thereby preventing the manufacturer from being able to test the condensing unit individually), the manufacturer must test, represent, and certify the matched refrigeration system as specified in this section. A component that is part of a certified matched pair and that has not been rated individually cannot be sold individually, nor can it be sold as part of a different matched pair (that is, with a different component matched to it) unless that new matched pair has also been tested and certified.

DOE requests comment on the revised representation requirements.

See section V.E for a list of issues on which DOE seeks comment.

3. Certification and Compliance Requirements

A manufacturer of a walk-in cooler or walk-in freezer is any person who: (1) Manufactures a component of a walk-in cooler or walk-in freezer that affects energy consumption, including, but not limited to, refrigeration, doors, lights, windows, or walls; or (2) manufactures or assembles the complete walk-in cooler or walk-in freezer. 10 CFR 431.302.

Several of the statutory standards, as well as DOE's 2014 standards and any energy conservation standards that DOE may adopt in its separate ongoing rulemaking (see Docket No. EERE–2015–BT–STD–0016) apply to specific components of a walk-in. A manufacturer of a walk-in component (*i.e.,* part 1 of the definition of a manufacturer of a walk-in cooler or walk-in freezer) is the entity that manufactures, produces, assembles or imports a walk-in panel, door or refrigeration system. A manufacturer of a walk-in component is responsible for ensuring the compliance of the component(s) it manufactures. DOE requires a manufacturer of a walk-in component to certify the compliance of the components it manufactures.

A manufacturer of a complete walk-in (*i.e.,* part 2 of the definition of a manufacturer of a walk-in cooler or walk-in freezer) is the entity that manufactures, produces, assembles or imports a walk-in cooler or freezer (*i.e.,* an enclosed storage space meeting the definition of a walk-in cooler or freezer). In some cases, this may be an "installer." Although DOE does not require a manufacturer of a complete walk-in to certify the compliance of the "box" as a whole, a manufacturer of a complete walk-in must ensure that the walk-in meets applicable statutory and/or regulatory standards. If a manufacturer of a complete walk-in also meets part 1 of the definition (*i.e.,* also manufactures individual components), then it must certify the compliance of the components it manufactures. Compliance responsibilities for manufacturers of complete walk-ins are discussed in more detail later in this section.

a. Manufacturers of Walk-in Components

A manufacturers of a walk-in component must ensure that the component(s) meet applicable standard(s). DOE is proposing to maintain its current component-based approach for compliance certification. Manufacturers of walk-in components must currently submit a certification report to the Department as described in 10 CFR 429.12 and 10 CFR 429.53(b) to certify compliance with the standards for which compliance is currently required. Namely:

—Manufacturers of doors for walk-in coolers or walk-in freezers must report the door type, R-value of the door insulation, and a declaration that the manufacturer has incorporated the applicable design requirements. In addition, manufacturers of transparent reach-in doors and windows for walk-ins must report the glass type of the doors and windows (such as double-pane with heat reflective treatment or triple-pane glass with gas fill), as well as the power draw of the antisweat heater in watts per square foot of door opening.

—Manufacturers of walk-in cooler or walk-in freezer panels must report the R-value of the insulation.

—Manufacturers of refrigeration systems for walk-ins must report each motor's purpose (that is, whether the motor is an evaporator fan motor or a condenser fan motor), the motor's horsepower, and a declaration that the manufacturer has incorporated the applicable design requirements.

DOE generally plans to retain these existing requirements. However, DOE proposes to amend the provisions at 10 CFR 429.12(b)(6) that require walk-in manufacturers to submit the basic model number for each walk-in brand. Instead, DOE proposes that for each brand, a walk-in manufacturer must submit both the basic model number and the manufacturer's individual model number(s). DOE elected to limit walk-in manufacturer's reporting requirements in a March 2011 rulemaking revising DOE's certification, compliance, and enforcement regulations for certain consumer products and commercial and industrial equipment including walk-ins. At the time, DOE stated it did not have sufficient information to determine whether reporting of individual model numbers for walk-in components was feasible, but that it would revisit this issue in a future rulemaking. 76 FR 12422, 12446 (March 7, 2011). Since the March 2011 rulemaking, manufacturers have routinely submitted both basic model numbers and individual model numbers for walk-in refrigeration systems, panels, and doors. The collected information suggests that it is feasible for manufacturers to certify both basic model numbers and individual model numbers for each brand.[7] Accordingly, this proposal would require that a walk-in manufacturer provide individual model number(s) as part of its reporting submission.

In this NOPR, DOE also proposes to add reporting requirements for both the standards promulgated in the June 2014 final rule (with a June 2017 compliance date) and for the forthcoming proposed standards for certain equipment classes of walk-in refrigeration systems that will be defined in a separate energy conservation standards rulemaking (see Docket No. EERE–2015–BT–STD–0016).

In addition to the reporting requirements defined in 10 CFR 429.53(b), DOE proposes to require certification reports to include the following public product-specific information to show compliance with the amended energy conservation standards:

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[7] Public certification information for walk-in refrigeration systems, panels, and doors can be found at *https://www.regulations.doe.gov/certification-data/.*

—Doors: Rated energy consumption, and rated surface area in square feet.
—Refrigeration systems: Rated annual walk-in energy factor (AWEF), rated net capacity, and the configuration tested for certification (*e.g.,* condensing unit only, unit cooler only, or matched pair).

To enable DOE to verify a door's represented energy consumption, DOE proposes to require door manufacturers to certify additional product specific information that would not be published on the DOE Web site. Specifically, DOE proposes to require door manufacturers to certify the rated power of each light, heater wire, and other electricity consuming device associated with each model of display and non-display door and whether the device(s) has a timer, control system, or other demand-based control reducing the device's power consumption.

If adopted, these reporting requirements would need to be used by walk-in component manufacturers when certifying compliance with the amended energy conservation standards for doors refrigeration systems.

b. Manufacturers of Complete Walk-Ins

Although DOE does not require manufacturers of complete walk-ins to submit certification reports, a manufacturer of a complete walk-in must ensure that each walk-in it manufactures meets the various statutory and regulatory standards. That is, a manufacturer of a complete walk-in is required to use components that comply with the applicable standards and to ensure the final product fulfills the statutory design requirements.

For example, consider an installer deciding which panels to use. The installer could assemble a compliant walk-in in several ways. The installer could build a panel, test it, and certify it as the component manufacturer. The installer could use an uncertified panel with a claimed compliant R-value and accept responsibility for its compliance. The installer could use a certified panel with a label and bear no responsibility for the compliance of the panel. In any of these situations, the installer must use compliant panels. The only difference between the 3 scenarios is that in the third scenario the installer is permitted to rely upon the representations of the manufacturer of a WICF component to ensure compliance; if those representations turn out to be false, the component manufacturer is responsible.

As discussed in more detail in III.B.5, DOE is proposing several provisions to help manufacturers of complete walk-ins, who are not manufacturers of walk-in components, ensure compliance with the standards. In addition to the component requirements for which DOE requires certification (doors, panels, and refrigeration systems), walk-ins generally must: Have automatic door closers; have strip doors, spring hinged doors, or other method of minimizing infiltration when doors are open; and for all interior lights, use light sources with an efficacy of 40 lumens per watt or more. It is the responsibility of the manufacturer of the complete walk-in to ensure that the walk-in incorporates these design features.

DOE seeks comment on the proposed additions to the reporting requirements. See section V.E for a list of issues on which DOE seeks comment.

4. Enforcement Provisions

a. Sampling Plan for Enforcement Testing of Covered Equipment and Certain Low-Volume Covered Products

DOE is proposing to include walk-ins to the list of equipment subject to the enforcement testing sampling plan for covered equipment found in Appendix B of Subpart C of Part 429.

b. Equipment-Specific Enforcement Provisions

DOE proposes to add specific enforcement provisions for walk-in refrigeration systems to 10 CFR 429.134. Specifically, DOE proposes to clarify which entity or entities are liable for the distribution of noncompliant units in commerce, as well as to explain how the Department verifies refrigeration capacity for walk-in refrigeration systems.

If DOE determines that a basic model of a panel, door, or refrigeration system for walk-ins fails to meet an applicable energy conservation standard, then the manufacturer of that basic model is responsible for the consequences flowing from that noncompliance. If DOE determines that a complete walk-in cooler or walk-in freezer or any component thereof fails to meet an applicable energy conservation standard, then the manufacturer of that complete walk-in cooler or walk-in freezer is responsible for the noncompliance with the applicable standard. However, a manufacturer of a complete walk-in would not be held responsible for the use of components that were certified and labeled as compliant but later found to be noncompliant with the applicable standards.

DOE also proposes to add an explanation of how the Department verifies refrigeration capacity for walk-in refrigeration systems to 10 CFR 429.134. The refrigeration capacity of the basic model will be measured pursuant to the test requirements of 10 CFR part 431 for each unit tested. The results of the measurement(s) will be averaged and compared to the value of refrigeration capacity certified by the manufacturer. The certified refrigeration capacity will be considered valid only if the average measured refrigeration capacity is within 5 percent of the certified refrigeration capacity. If the certified refrigeration capacity is found to be valid, that refrigeration capacity will be used as the basis for calculating annual energy consumption for the basic model. If the certified refrigeration capacity is found to be invalid, the average measured refrigeration capacity will serve as the basis for calculating annual energy consumption for the basic model.

Further, DOE proposes to specify how DOE will verify the surface area for walk-in display doors and non-display doors in 10 CFR 429.134. The certified surface area will be considered valid only if the average measured surface area of the door is within 1 percent of the certified surface area. If the certified surface area is found to be valid, that surface area will be used as the basis for calculating maximum energy consumption for the basic model. If the certified surface area is found to be invalid, the average measured surface area will serve as the basis for calculating maximum energy consumption for the basic model.

In addition, DOE proposes to specify in 10 CFR 429.134 how DOE will account for the rated power (as defined in this proposal) of each electricity consuming device(s) in calculating the walk-in door energy consumption. For each basic model of walk-in cooler and freezer door, DOE will calculate the door's energy consumption using the power listed on the nameplate of each electricity consuming device shipped with the door. If an electricity consuming device shipped with a walk-in door does not have a nameplate or such nameplate does not list the device's power, then DOE will use the device's "rated power" included in the door's certification report.

DOE seeks comment on the proposed method for verifying the capacity of walk-in refrigeration systems and the surface area of walk-in doors.

See section V.E for a list of issues on which DOE seeks comment.

5. Labeling Requirements

If the Secretary has prescribed test procedures for any class of covered equipment, a labeling rule applicable to such class of covered equipment must be prescribed. See 42 U.S.C. 6315(a). EPCA, however, also sets out certain criteria that must be met prior to prescribing a given labeling rule. Specifically, to establish these requirements, DOE must determine that: (1) Labeling in accordance with Section 6315 is technologically and economically feasible with respect to any particular equipment class; (2) significant energy savings will likely result from such labeling; and (3) labeling in accordance with Section 6315 is likely to assist consumers in making purchasing decisions. (42 U.S.C. 6315(h))

If these criteria are met, EPCA specifies certain aspects of equipment labeling that DOE must consider in any rulemaking establishing labeling requirements for covered equipment. At a minimum, such labels must include the energy efficiency of the affected equipment, as tested under the prescribed DOE test procedure. The labeling provisions may also consider the addition of other requirements, including: directions for the display of the label; a requirement to display on the label additional information related to energy efficiency or energy consumption, which may include instructions for maintenance and repair of the covered equipment, as necessary, to provide adequate information to purchasers; and requirements that printed matter displayed or distributed with the equipment at the point of sale also include the information required to be placed on the label. (42 U.S.C. 6315(b) and 42 U.S.C. 6315(c))

DOE proposes to establish labeling requirements for walk-in cooler and freezers. Specifically, DOE proposes to require certain information, and the display of this required information, for door, panel, and refrigeration system nameplates. DOE also proposes to clarify requirements with respect to the disclosure of efficiency information in marketing materials and the labeling requirements for process cooling refrigeration systems.

DOE proposes that the permanent nameplates of doors for walk-in coolers and walk-in freezers must be clearly marked with the rated energy consumption, the door brand, the door model number, the date of manufacture of the door, and the statement, "This door is designed and certified for use in walk-in cooler and freezer applications." Specifically, the energy consumption must be identified in the form "EC____," and the model number must be displayed in one of the following forms: "Model____", "Model number____", or "Model No.____".

DOE proposes that the permanent nameplates of panels for walk-in cooler and walk-in freezers must be clearly marked with the rated R-value, the panel model number, the date of manufacture of the panel, and the statement, "This panel is designed and certified for use in walk-in cooler and freezer applications." The R-value must be identified in the form "R-value____," and the model number must be displayed in one of the following forms: "Model____", "Model number____", or "Model No. ____".

DOE proposes that the permanent nameplates of refrigeration systems for walk-in coolers and walk-in freezers (that are not manufactured solely for process cooling applications) must be clearly marked with the AWEF, refrigeration system brand, refrigeration system model number, the date of manufacture of the refrigeration system, and the statement, "This refrigeration system is designed and certified for use in walk-in cooler and freezer applications." The AWEF must be identified in the form "AWEF ____", and the model number must be displayed in one of the following forms: "Model____", "Model number____", or "Model No. ____". In addition, DOE proposes that the permanent nameplate of a refrigeration system component that can only be used as part of a process cooling refrigeration system must be marked clearly with the refrigeration system brand, refrigeration system model number, the date of manufacture of the refrigeration system, and the statement, "This refrigeration system is designed only for use in walk-in cooler and freezer process cooling refrigeration applications." The model number must be displayed in one of the following forms: "Model ____", "Model number____", or "Model No.____". If a refrigeration system can be used for both process cooling refrigeration and other types of refrigeration for walk-in cooler and freezer applications, then it must be clearly marked with the AWEF, refrigeration system brand, refrigeration system model number, the date of manufacture of the refrigeration system, and the statement, "This refrigeration system is designed and certified for use in walk-in cooler and freezer applications."

For walk-in panels, doors, and refrigeration systems, DOE proposes that all orientation, spacing, type sizes, typefaces, and line widths to display this required information must be the same as or similar to the display of the other performance data contained on the component's permanent nameplate. DOE is also considering a requirement specifying the location of the permanent nameplates on doors, panels, and refrigeration systems. Specifically, that the permanent nameplate must be visible at all times, including when the component is assembled into a complete walk-in.

DOE proposes to clarify the requirements for the disclosure of efficiency information in marketing materials and to require that such marketing materials must prominently display the same information that must appear on a walk-in cooler or walk-in freezer component's permanent nameplate.

DOE has reviewed the proposed labeling requirements with respect to the three requirements in EPCA restricting the Secretary's authority to promulgate labeling rules and has made the following findings. (42 U.S.C. 6315(h))

First, the proposed labeling recommendations are technologically and economically feasible with respect to each equipment class in this rulemaking. In general, DOE has found that walk-in refrigeration system manufacturers and display door manufacturers include nameplates on their equipment, and typically these nameplates include the equipment's model number. DOE believes it is technologically feasible for refrigeration system and display door manufacturers to include energy efficiency or energy consumption information on the label without increasing the size of the label. DOE expects that the cost to do so would be negligible. Accordingly, in DOE's view, requiring that labels provide this information would be economically feasible as well.

DOE has found, however, that it is less common for non-display doors and panels for walk-ins to have nameplates. DOE understands that, while an entire assembled walk-in cooler or freezer may have a nameplate, each individual panel and non-display door making up a walk-in cooler or freezer may not be labeled. Nonetheless, DOE expects that adding a permanent nameplate or permanent sticker to both walk-in non-display doors and panels is technologically feasible, as both types of equipment have adequate useable surface to apply such labels. DOE estimated that the total cost of applying labels to non-display doors and panels would be negligible—less than a tenth of one percent of the average manufacturer's annual revenue—and the labeling requirements are thus economically feasible.

DOE also considered the cost to manufacturers of updating their marketing materials to include efficiency information. Marketing materials include literature, data sheets, selection software, sales training, and compliance documentation. Based on marketing conversion costs for other commercial equipment, DOE estimates that manufacturers may incur costs of up to $10,000 per model to update marketing materials for walk-in components. Panel and door manufacturers typically only produce a few distinct models of their walk-in equipment, and DOE estimated that marketing-related conversion costs for these components would total less than one percent of industry annual revenue attributed to sales of walk-in equipment. Refrigeration manufacturers often produce a large number of distinct basic models—several have certified up to 100 basic models of refrigeration systems on DOE's Compliance Certification Management System ("CCMS") Web site. DOE estimates that marketing-related conversion costs for walk-in refrigeration systems could total approximately one percent of industry annual revenue attributed to sales of walk-in equipment. However, many companies that manufacture walk-in refrigeration systems also make several other types of products, with walk-in equipment comprising a small portion of their overall revenues. Given these estimates, DOE tentatively concludes that updating marketing materials is economically feasible for manufacturers of walk-in equipment.

DOE also examined the impact of these new requirements on small manufacturers. For further discussion, see section IV.B.2.

Second, DOE believes the proposed labeling requirements would likely result in significant energy savings. The related energy conservation standards are expected to save approximately 3 quadrillion British thermal units (quads). Requiring labels that include the rated value subject to the standards will increase consumer awareness of the standards. As a result, requiring the labels may increase consumer demand for more efficient walk-in components, thus leading to additional savings beyond that calculated for the standards. In addition, labeling requirements would help installers, assemblers, and contractors ensure that they are selecting equipment that the component manufacturer intended to be used as part of a completed walk-in, and would limit the potential compliance burden faced by these entities. For example, insulated metal panels may be used in other types of applications, such as communications equipment sheds. Labeling requirements differentiate walk-in cooler and freezer panels from other types of insulated metal panels that are not appropriate for use in walk-ins.

Third, DOE finds that the proposed labeling requirements are likely to assist consumers in making purchasing decisions. By including the rated metric on the nameplate and marketing materials, manufacturers will be able to demonstrate to purchasers that the equipment they are purchasing meets the DOE standard and is acceptable for use in a walk-in. Additionally, consumers will have the information needed to compare the energy efficiency performance between different component models, with the assurance that the ratings were calculated according to a DOE-specified test procedure.

DOE seeks comment on the proposed requirements for manufacturers to label their walk-in equipment and update their marketing materials for walk-in equipment to include efficiency information. DOE also seeks comment on whether it should add a requirement specifying that the permanent nameplates on doors, panels, and refrigeration systems be visible at all times, including when the component is assembled into a complete walk-in. Further, DOE asks whether these requirements are technologically and economically feasible. DOE particularly seeks data from manufacturers regarding the cost of labeling and updating marketing materials.

See section V.E for a list of issues on which DOE seeks comment.

C. Compliance With Other EPCA Requirements

In addition to the issues discussed in this preamble, DOE examined its other obligations under EPCA in developing the amendments in this proposal. These requirements are addressed in greater detail below.

1. Test Burden

EPCA requires that the test procedures DOE prescribes or amends be reasonably designed to produce test results that measure the energy efficiency, energy use, or estimated annual operating cost of a covered product during a representative average use cycle or period of use. These procedures must also not be unduly burdensome to conduct. See 42 U.S.C. 6293(b)(3) and 42 U.S.C. 6316(a). DOE has concluded that the proposed amendments satisfy this requirement. The proposed test procedure amendments represent minor changes to the test procedure that do not affect the equipment required for testing and either reduce or have no effect on the time required to conduct the testing. These amendments include the removal of the rating method for refrigeration systems with hot gas defrost, the requirement that certified ratings of refrigeration systems with adaptive defrost shall not include the benefit of the adaptive defrost feature, and the requirement that certified ratings of unit coolers with on-cycle variable-speed fan controls shall not include the benefit of this feature.

Section III.A.2.a discusses the reasons for removing the method for measuring the benefit of hot gas defrost from the test procedure. Currently, the test procedure for this feature consists of a calculation to represent the efficiency improvement of hot gas defrost as a credit applied to any low-temperature refrigeration system that includes it. No testing is required to validate the performance of the feature and thus there is no test burden involved. Likewise, there is no change in test burden associated with removing this calculation method.

Section III.A.2.b discusses DOE's revisions to the test procedure for refrigeration systems with adaptive defrost. Currently, manufacturers may certify the potential energy efficiency benefit of including adaptive defrost by either testing the feature or by using a calculation to represent the efficiency improvement of systems with this feature without testing. DOE is proposing to modify the test procedure to specify that certified ratings of systems with this feature shall exclude the benefit of the adaptive defrost feature. Because manufacturers currently have the option to use the calculation method to rate systems with this feature, there is no test burden involved because no validation testing is required; removing the ability to certify this feature would not have any effect on the associated test burden.

Section III.A.2.c discusses DOE's revisions to the test procedure for unit coolers with on-cycle variable-speed fan control. DOE currently allows manufacturers to test the benefit of this feature using the DOE test procedure for unit coolers. DOE is proposing to modify the test procedure to specify that certified ratings of systems with this feature shall exclude the benefit. This approach lowers the testing burden for unit coolers with this feature, because manufacturers would no longer perform this test to obtain ratings for certification. (Manufacturers may still make representations of unit cooler efficiency with this feature; in this case, the testing burden would not change.)

2. Changes in Measured Energy Use

When DOE modifies test procedures, it must determine to what extent, if any, the new test procedure would alter the measured energy use of covered products. (42 U.S.C. 6293(e)(1)). DOE has tentatively determined that the proposed test procedure amendments could affect the measured energy use of certain covered products, but the amendments would only affect aspects related to testing after the compliance date of the amended energy conservation standards that DOE is proposing in a separate notice. The test procedure amendments would not affect the current standards for any walk-in components, nor would they affect the standards promulgated in the June 2014 final rule with a compliance date of June 5, 2017. The standards with a compliance date in 2017 apply to medium-temperature, dedicated condensing refrigeration systems, while the test procedure modifications would only affect low-temperature systems and unit coolers. In the rulemaking analysis for the standards that DOE is proposing separately, DOE is accounting for the test procedure changes being proposed in this notice. Therefore, the modifications to the test procedure that DOE is proposing herein will require no further changes to the energy conservation standards.

DOE requests comment on its determination that this proposal would not introduce any changes that increase test burden or alter the measured energy use of walk-in equipment.

See section V.E for a list of issues on which DOE seeks comment.

3. Cost and Burden Impact on WICF Manufacturers

As explained in section III.B.3, a manufacturer of a walk-in cooler or walk-in freezer is any person who: (1) Manufactures a component of a walk-in cooler or walk-in freezer that affects energy consumption, including, but not limited to, refrigeration, doors, lights, windows, or walls; or (2) manufactures or assembles the complete walk-in cooler or walk-in freezer. 10 CFR 431.302. DOE has proposed to add clarifications that the entity responsible for testing, rating, and certifying is the WICF component manufacturer. Thus, WICF manufacturers that exclusively assemble the complete WICF do not bear the testing and certification burden. DOE is also proposing labeling and revisions to the certification requirements on WICF component manufacturers in this proposed rule. The addition of these proposals, if adopted, will reduce any burden on WICF manufacturers that manufacture or assemble the complete walk-in cooler or walk-in freezer by allowing them to more easily identify compliant WICF components for assembly. This is the compliance regime in place today, which is unchanged by this proposal; however, DOE believes labeling will help WICF assemblers comply with the regulations. In conclusion, DOE does not believe that there is any burden added on WICF manufacturers that assemble complete WICFs as a result of performance-based testing requirements. While DOE did not assess the impact on these manufacturers in the final rules pertaining to walk-in cooler and walk-in freezer test procedures published in April 2011 and May 2014, DOE expects this assessment holds true for those final rules as well. 76 FR 21605 and 79 FR 27412.

IV. Procedural Issues and Regulatory Review

A. Review Under Executive Order 12866

The Office of Management and Budget (''OMB'') has determined that test procedure rulemakings do not constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866, Regulatory Planning and Review, 58 FR 51735 (October 4, 1993). Accordingly, this action was not subject to review under the Executive Order by the Office of Information and Regulatory Affairs (''OIRA'') in the Office of Management and Budget.

B. Review Under the Regulatory Flexibility Act

The Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) requires preparation of an initial regulatory flexibility analysis (IFRA) for any rule that by law must be proposed for public comment, unless the agency certifies that the rule, if promulgated, will not have a significant economic impact on a substantial number of small entities. As required by Executive Order 13272, ''Proper Consideration of Small Entities in Agency Rulemaking,'' 67 FR 53461 (August 16, 2002), DOE published procedures and policies on February 19, 2003, to ensure that the potential impacts of its rules on small entities are properly considered during the DOE rulemaking process. 68 FR 7990. DOE has made its procedures and policies available on the Office of the General Counsel's Web site: *http://energy.gov/gc/office-general-counsel.* DOE has prepared the following IRFA for the equipment that are the subject of this rulemaking.

For manufacturers of walk-in equipment, the Small Business Administration (''SBA'') has set a size threshold, which defines those entities classified as ''small businesses'' for the purposes of the statute. DOE used the SBA's small business size standards to determine whether any small entities would be subject to the requirements of the rule. 65 FR 30848 (May 15, 2000), as amended at 65 FR 53533, 53544 (September 5, 2000) and codified at 13 CFR part 121. The size standards are listed by North American Industry Classification System (''NAICS'') code and industry description and are available at *http://www.sba.gov/category/navigation-structure/contracting/contracting-officials/small-business-size-standards.* Walk-in equipment is classified under NAICS 333415, ''Air-Conditioning and Warm Air Heating Equipment and Commercial and Industrial Refrigeration Equipment Manufacturing.'' The SBA sets a threshold of 1,250 employees or less for an entity to be considered as a small business for this category. Based on this threshold, DOE presents the following IRFA analysis:

1. Description and Estimated Number of Small Businesses Regulated

DOE used available public information to identify potential small manufacturers. DOE's research involved industry trade association membership directories (including AHRI Directory,[8] and NAFEM,[9]) public databases (*e.g.* the SBA Database,[10]) individual company Web sites, and market research tools (*e.g.,* Dun and Bradstreet reports [11] and Hoovers reports) [12] to create a list of companies that manufacture or sell equipment covered by this rulemaking. During the 2014 rulemaking, DOE also asked stakeholders and industry representatives if they were aware of any other small manufacturers during manufacturer interviews and at DOE public meetings. DOE reviewed publicly available data and contacted select companies on its list, as necessary, to determine whether they met the SBA's definition of a small business manufacturer of covered walk-in coolers and walk-in freezers. DOE screened out companies that do not offer equipment covered by this rulemaking, do not meet the definition of a "small business," or are foreign-owned.

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[8] See *www.ahridirectory.org/ahriDirectory/pages/home.aspx.*

[9] See *http://www.nafem.org/find-members/MemberDirectory.aspx.*

[10] See *http://dsbs.sba.gov/dsbs/search/dsp_dsbs.cfm.*

[11] See *www.dnb.com/.*

[12] See *www.hoovers.com/.*

DOE identified forty-seven panel manufacturers and found forty-two of the identified panel manufacturers to be small businesses.

DOE identified forty-nine walk-in door manufacturers. Forty-five of those produce solid doors and four produce display doors. Of the forty-five solid door manufacturers, forty-two produce panels as their primary business and are considered in the category of panel manufacturers in this preamble. The remaining three solid door manufacturers are all considered to be small businesses. Of the four display door manufacturers, two are considered small businesses. Therefore, of the seven manufacturers that exclusively produce walk-in doors (three producing solid doors and four producing display doors), DOE determined that five are small businesses.

DOE identified nine walk-in refrigeration system manufacturers that produce equipment for one or more of the equipment classes analyzed in this proposal. All nine are domestic companies. Two of the nine manufacturers are small businesses.

Lastly, DOE looked at manufacturers that assemble the complete walk-in cooler or walk-in freezer (*i.e.*, an installer). Walk-in installation work is a subset of the highly fragmented heating, ventilation, air-conditioning, and refrigeration (HVACR) industry. DOE was unable to identify any company that exclusively operated as an assembler of WICFs. In general, WICF assemblers offer walk-in installation as part of a broader refrigeration offering and/or broader heating and cooling offering.

DOE estimates that 10,000 to 30,000 companies offer walk-in contractor services. This is a subset of the roughly 100,000 companies that make up the domestic HVACR contractor industry. Key activities for these companies include the installation of residential HVAC, commercial HVAC, commercial refrigeration, and industrial refrigeration systems. Of these, DOE estimates the majority are small.

2. Description and Estimate of Compliance Requirements

Panel manufacturers have had to comply with standards for their panels' R-value (a measure of the insulating value) since 2009. In a previous test procedure rule, published in May 2014, DOE established a sampling plan and certification reporting requirements for walk-in panels. 79 FR 27388 (May 13, 2014). DOE is not proposing any new testing, certification, compliance, or reporting requirements in this NOPR. However, DOE is proposing labeling requirements for walk-in panels, and is also proposing that manufacturers must include rating information on marketing materials for panels. For further discussion of the proposed labeling requirements, see section III.B.5. As discussed in that section, the cost of updating marketing materials could be up to $10,000 per panel model, but manufacturers—including small manufacturers—tend to produce only a few distinct panel models. DOE calculated that the cost of updating marketing materials for a small manufacturer would be less than one percent of annual revenues; thus, this requirement would not have a significant impact on small manufacturers.

DOE is proposing new certification requirements for door manufacturers and refrigeration system manufacturers to certify their basic models to DOE. Door manufacturers must certify that they meet the June 2014 standards, which have a compliance date of June 5, 2017. Manufacturers of refrigeration systems for which standards were promulgated in the June 2014 final rule, and which were not subsequently remanded by the United States Court of Appeals for the Fifth Circuit's court order, must also certify that those refrigeration systems meet the June 2014 standards, which have a compliance date of June 5, 2017. DOE is conducting a separate energy conservation standards rulemaking for those refrigeration system classes whose standards were remanded. On the compliance date for those standards, manufacturers will have to certify that those refrigeration systems meet the relevant standards using the certification requirements being proposed in this rule.

In general, DOE is proposing to modify the data elements walk-in door manufacturers and walk-in refrigeration system manufacturers submit as part of a certification report indicating that all basic models distributed in commerce in the U.S. comply with the applicable standards using DOE's testing procedures, in include product-specific certification data describing the efficiency and characteristics of the basic model. The certification reports are submitted for each basic model, either when the requirements go into effect (for models already in distribution), or when the manufacturer begins distribution of a particular basic model, and annually thereafter. Reports must be updated when a new model is introduced or a change affecting energy efficiency or use is made to an existing model resulting in a change in the certified rating. (10 CFR 429.12(a))

DOE currently requires manufacturers or their party representatives to prepare and submit certification reports using DOE's electronic Web-based tool, the Compliance Certification Management System ("CCMS"), which is the only mechanism for submitting certification reports to DOE. CCMS currently has product-specific templates that manufacturers must use when submitting certification data to DOE. See *http://www.regulations.doe.gov/ccms*. This proposed rule would not change the requirement that manufacturers submit certification reports electronically. DOE believes the availability of electronic filing through the CCMS system reduces reporting burdens, streamlines the process, and provides the Department with needed information in a standardized, more accessible form. This electronic filing system also ensures that records are recorded in a permanent, systematic way.

DOE is also proposing to require manufacturers to label their doors and refrigeration systems with product-specific data and information describing the efficiency and characteristics of the basic model, and is also proposing that manufacturers must include rating information on marketing materials for these components. For further discussion of the proposed labeling requirements, see section III.B.5. As discussed in that section, the cost of updating marketing materials could be up to $10,000 per basic model. Door manufacturers—including small manufacturers—tend to produce only a few distinct door models; thus, this requirement would not have a significant impact on small door manufacturers. Small refrigeration manufacturers, on the other hand, may produce up to 100 basic models of refrigeration systems—as many as large manufacturers. The cost of updating marketing materials is a one-time expense that varies greatly by product offering.

DOE is proposing to add clarifications that the entity responsible for testing, rating, and certifying is the WICF component manufacturer. Thus, WICF manufacturers that exclusively assemble the complete WICF do not bear the testing and certification burden. DOE is also proposing labeling and revisions to the certification requirements on WICF component manufacturers in this proposed rule. The addition of these proposals, if adopted, will reduce any burden on WICF manufacturers that manufacture or assemble the complete walk-in cooler or walk-in freezer by allowing them to more easily identify compliant WICF components for assembly. This does not change the compliance requirements for these WICF manufacturers and installers; however, DOE believes labeling will help WICF assemblers comply with the regulations. In conclusion, DOE does not believe that small WICF manufacturers that assemble complete WICFs will see an increased burden from the proposals in this rulemaking.

3. Duplication, Overlap, and Conflict With Other Rules and Regulations

DOE is not aware of any rules or regulations that duplicate, overlap, or conflict with the rule being considered in this NOPR.

4. Significant Alternatives to the Rule

This section considers alternatives to the proposals in this document. DOE has tried to minimize the reporting burden as much as possible by: (1) Accepting electronic submissions; (2) providing preformatted templates that lay out the certification and compliance requirements for each product; and (3) allowing manufacturers to group individual models into basic models for the purposes of certification to reduce the number of discrete models reported to the Department. DOE has also made efforts to address the concerns of small businesses by expanding the ability of manufacturers to use alternative efficiency determination methods ("AEDMs") in lieu of testing equipment.

DOE seeks input on its Initial Regulatory Flexibility Analysis from businesses that would be affected by this rulemaking and will consider comments received in the development of any final rule.

See section V.E for a list of issues on which DOE seeks comment.

C. Review Under the Paperwork Reduction Act of 1995

Under the Paperwork Reduction Act of 1995 ("PRA") (44 U.S.C. 3501, *et seq.*), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct, sponsor, or require through regulations. DOE established regulations for the certification and recordkeeping requirements for all covered consumer products and commercial equipment, including walk-in coolers and walk-in freezers. See generally 10 CFR part 429. This requirement has been approved by OMB for walk-ins under OMB control number 1910–1400. This proposal would expand the information that manufacturers and importers of covered walk-in equipment would need to submit to the Department as part of a certification that the products they are distributing in commerce in the U.S. comply with the applicable energy conservation standards. Further, this proposal requires manufacturers to disclose performance information as part of the proposed labeling requirements for walk-in panels, doors, and refrigeration systems.

In compliance with the PRA, DOE is seeking comment on this proposed expansion of the existing information collection.

Agency: U.S. Department of Energy (DOE).

OMB Control Number: OMB No. 1910–1400.

Information Collection Request Title: Certification Reports, Compliance Statements, Application for a Test Procedure Waiver, Recordkeeping for Consumer Products and Commercial/Industrial Equipment Subject to Energy or Water Conservation Standards, and Label and Marketing Material Information Disclosure.

Type of Request: Revision and Expansion of an Existing Collection.

Requested Expiration Date of Approval: Three years from the date of approval.

Purpose: Manufacturers of the covered products addressed in this NOPR are already required to certify to DOE that their equipment complies with applicable energy conservation standards. In certifying compliance, manufacturers must test their equipment according to the applicable DOE test procedures for the given equipment type, including any amendments adopted for those test procedures, or use AEDMs (as applicable) to develop the certified ratings of the basic models. The collection-of-information requirement for the certification proposals is subject to review and approval by OMB under the PRA.

Manufacturers are required to certify: (1) New basic models before distribution in commerce; (2) existing basic models, whose certified ratings remain valid, annually; (3) existing basic models, whose designs have been altered resulting in a change in rating that is more consumptive or less efficient, at the time the design change is made; and (4) previously certified basic models that have been discontinued annually. Respondents may submit reports to the Department at any time during the year using DOE's online system.

Amendments to the existing walk-in standards are expected to result in slight changes to the information that DOE is proposing to collect for walk-ins. Specifically, DOE is proposing that, in addition to information currently required for certification reports, door manufacturers report the door energy use as determined by the DOE test procedure, the rated power of each light, heater wire and/or other electricity consuming device and whether such device(s) has a control system. Refrigeration system manufacturers report the Annual Walk-in Efficiency Factor ("AWEF"), net capacity as determined by the DOE test procedure, and the configuration test for certification. Manufacturers will have to re-submit certification reports for basic models that they distribute in commerce starting on the compliance date of the amended standards.

In addition, DOE proposed to add labeling requirements for walk-in panels, doors, and refrigeration systems. Specifically, each of these components will be required to disclose on its permanent nameplate the rated energy use or efficiency, as applicable, brand, model number, and date of manufacture. In addition, each component label must include a statement indicating that the component is designed and certified for use in walk-in cooler and freezer applications. See section III.B.5 for the specific labeling requirements for each component.

DOE estimated that it will take each respondent (walk-in component manufacturer) approximately 1 hour total per company per year to comply with the information disclosure (*i.e.,* labeling) requirements based on 0.25 hours of technician/technical work to apply the label and 0.75 hours clerical work to create the label and update marketing materials. For the purposes of estimating burden, DOE determined from its Compliance Certification Database that each panel manufacturer and door manufacturer certifies on average 4 basic models and that each basic model will require a discrete label. Based on DOE's Compliance Certification Database, each refrigeration manufacturer certifies approximately 100 basic models and DOE is conservatively estimating that each basic model will require a unique label.

Regarding the additional certification requirements, DOE estimates that the slight change in certification requirements would not result in additional burden because walk-in component manufacturers are already required to annually certify compliance with the existing standards.

DOE estimates the burden for this rule as follows:

(1) *Annual Estimated Number of Respondents:* 63 (47 panel manufacturers, 7 door manufacturers,

and 9 refrigeration system manufacturers);

(2) *Annual Estimated Number of Total Responses:* 1,116 (188 for panels, 28 door, 900 for refrigeration systems);

(3) *Annual Estimated Number of Burden Hours:* 1,116 (1 hour for applying and creating label and updating marketing materials);

(4) *Annual Estimated Reporting and Recordkeeping Cost Burden:* $83,700.

DOE requests comment generally on its review under the PRA, and specifically on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology.

See section V.E for a list of issues on which DOE seeks comment.

Notwithstanding any other provision of the law, no person is required to respond to, nor shall any person be subject to a penalty for failure to comply with, a collection of information subject to the requirements of the PRA, unless that collection of information displays a currently valid OMB Control Number.

D. Review Under the National Environmental Policy Act of 1969

In this proposed rule, DOE proposes test procedure amendments that will likely be used to develop and implement future energy conservation standards for walk-in coolers and walk-in freezers. DOE has determined that this rule falls into a class of actions that are categorically excluded from review under the National Environmental Policy Act of 1969 (42 U.S.C. 4321 *et seq.*) and DOE's implementing regulations at 10 CFR part 1021. Specifically, this proposed rule would amend the existing test procedures without affecting the amount, quality or distribution of energy usage, and, therefore, would not result in any environmental impacts. Thus, this rulemaking is covered by Categorical Exclusion A5 under 10 CFR part 1021, subpart D, which applies to any rulemaking that interprets or amends an existing rule without changing the environmental effect of that rule. Accordingly, neither an environmental assessment nor an environmental impact statement is required.

E. Review Under Executive Order 13132

Executive Order 13132, "Federalism," 64 FR 43255 (August 4, 1999) imposes certain requirements on agencies formulating and implementing policies or regulations that preempt State law or that have Federalism implications. The Executive Order requires agencies to examine the constitutional and statutory authority supporting any action that would limit the policymaking discretion of the States and to carefully assess the necessity for such actions. The Executive Order also requires agencies to have an accountable process to ensure meaningful and timely input by State and local officials in the development of regulatory policies that have Federalism implications. On March 14, 2000, DOE published a statement of policy describing the intergovernmental consultation process it will follow in the development of such regulations. (65 FR 13735). DOE has examined this proposed rule and has determined that it would not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. EPCA governs and prescribes Federal preemption of State regulations as to energy conservation for the products that are the subject of this proposed rule. States can petition DOE for exemption from such preemption to the extent, and based on criteria, set forth in EPCA. (42 U.S.C. 6297(d)). No further action is required by Executive Order 13132.

F. Review Under Executive Order 12988

Regarding the review of existing regulations and the promulgation of new regulations, section 3(a) of Executive Order 12988, "Civil Justice Reform," 61 FR 4729 (February 7, 1996), imposes on Federal agencies the general duty to adhere to the following requirements: (1) Eliminate drafting errors and ambiguity, (2) write regulations to minimize litigation, (3) provide a clear legal standard for affected conduct rather than a general standard, and (4) promote simplification and burden reduction. Section 3(b) of Executive Order 12988 specifically requires that Executive agencies make every reasonable effort to ensure that the regulation (1) clearly specifies the preemptive effect, if any, (2) clearly specifies any effect on existing Federal law or regulation, (3) provides a clear legal standard for affected conduct while promoting simplification and burden reduction, (4) specifies the retroactive effect, if any, (5) adequately defines key terms, and (6) addresses other important issues affecting clarity and general draftsmanship under any guidelines issued by the Attorney General. Section 3(c) of Executive Order 12988 requires Executive agencies to review regulations in light of applicable standards in sections 3(a) and 3(b) to determine whether they are met or it is unreasonable to meet one or more of them. DOE has completed the required review and determined that, to the extent permitted by law, the proposed rule meets the relevant standards of Executive Order 12988.

G. Review Under the Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) requires each Federal agency to assess the effects of Federal regulatory actions on State, local, and Tribal governments and the private sector. Public Law 104–4, sec. 201 (codified at 2 U.S.C. 1531). For a proposed regulatory action likely to result in a rule that may cause the expenditure by State, local, and Tribal governments, in the aggregate, or by the private sector of $100 million or more in any one year (adjusted annually for inflation), section 202 of UMRA requires a Federal agency to publish a written statement that estimates the resulting costs, benefits, and other effects on the national economy. (2 U.S.C. 1532(a), (b)) The UMRA also requires a Federal agency to develop an effective process to permit timely input by elected officers of State, local, and Tribal governments on a proposed "significant intergovernmental mandate," and requires an agency plan for giving notice and opportunity for timely input to potentially affected small governments before establishing any requirements that might significantly or uniquely affect small governments. On March 18, 1997, DOE published a statement of policy on its process for intergovernmental consultation under UMRA. 62 FR 12820; also available at *http://energy.gov/gc/office-general-counsel.* DOE examined this proposed rule according to UMRA and its statement of policy and determined that the proposed rule contains neither an intergovernmental mandate, nor a mandate that may result in the expenditure of $100 million or more in any year, so these requirements do not apply.

H. Review Under the Treasury and General Government Appropriations Act, 1999

Section 654 of the Treasury and General Government Appropriations Act, 1999 (Pub. L. 105–277) requires Federal agencies to issue a Family Policymaking Assessment for any rule that may affect family well-being. This proposed rule would not have any impact on the autonomy or integrity of the family as an institution. Accordingly, DOE has concluded that it is not necessary to prepare a Family Policymaking Assessment.

I. Review Under Executive Order 12630

DOE has determined, under Executive Order 12630, "Governmental Actions and Interference with Constitutionally Protected Property Rights" 53 FR 8859 (March 18, 1988), that this proposed regulation would not result in any takings that might require compensation under the Fifth Amendment to the U.S. Constitution.

J. Review Under Treasury and General Government Appropriations Act, 2001

Section 515 of the Treasury and General Government Appropriations Act, 2001 (44 U.S.C. 3516 note) provides for agencies to review most disseminations of information to the public under guidelines established by each agency pursuant to general guidelines issued by OMB. OMB's guidelines were published at 67 FR 8452 (February 22, 2002), and DOE's guidelines were published at 67 FR 62446 (October 7, 2002). DOE has reviewed this proposed rule under the OMB and DOE guidelines and has concluded that it is consistent with applicable policies in those guidelines.

K. Review Under Executive Order 13211

Executive Order 13211, "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use," 66 FR 28355 (May 22, 2001), requires Federal agencies to prepare and submit to OMB, a Statement of Energy Effects for any proposed significant energy action. A "significant energy action" is defined as any action by an agency that promulgated or is expected to lead to promulgation of a final rule, and that (1) is a significant regulatory action under Executive Order 12866, or any successor order; and (2) is likely to have a significant adverse effect on the supply, distribution, or use of energy; or (3) is designated by the Administrator of OIRA as a significant energy action. For any proposed significant energy action, the agency must give a detailed statement of any adverse effects on energy supply, distribution, or use should the proposal be implemented, and of reasonable alternatives to the action and their expected benefits on energy supply, distribution, and use.

The proposed regulatory action to amend the test procedure for measuring the energy efficiency of walk-in coolers and walk-in freezers is not a significant regulatory action under Executive Order 12866. Moreover, it would not have a significant adverse effect on the supply, distribution, or use of energy, nor has it been designated as a significant energy action by the Administrator of OIRA. Therefore, it is not a significant energy action, and, accordingly, DOE has not prepared a Statement of Energy Effects.

L. Review Under Section 32 of the Federal Energy Administration Act of 1974

Under section 301 of the Department of Energy Organization Act (Pub. L. 95–91; 42 U.S.C. 7101), DOE must comply with section 32 of the Federal Energy Administration Act of 1974, as amended by the Federal Energy Administration Authorization Act of 1977. (15 U.S.C. 788; FEAA) Section 32 essentially provides in relevant part that, where a proposed rule authorizes or requires use of commercial standards, the notice of proposed rulemaking must inform the public of the use and background of such standards. In addition, section 32(c) requires DOE to consult with the Attorney General and the Chairman of the Federal Trade Commission (FTC) concerning the impact of the commercial or industry standards on competition.

The proposed modifications to the test procedure for walk-in coolers and walk-in freezers adopted in this final rule incorporates testing methods contained in certain sections of the following commercial standards: AHRI Standard 1250–2009, AHRI Standard 420–2008, and ASHRAE Standard 23.1–2010. DOE has evaluated these standards and is unable to conclude whether it fully complies with the requirements of section 32(b) of the FEAA (*i.e.,* whether it was developed in a manner that fully provides for public participation, comment, and review.) DOE will consult with both the Attorney General and the Chairman of the FTC concerning the impact of these test procedures on competition, prior to prescribing a final rule.

M. Description of Materials Incorporated by Reference

In this NOPR, DOE proposes to incorporate by reference AHRI 420–2008, titled "Performance Rating of Forced-Circulation Free Delivery Unit Coolers for Refrigeration." AHRI 420–2008 establishes the following elements for forced-circulation free-delivery unit coolers for refrigeration: Definitions, test requirements, rating requirements, minimum data requirements for published ratings, marketing and nameplate data, and conformance conditions. The standard applies to forced-circulation, free-delivery unit coolers, as defined in Section 3 of this standard, operating with a volatile refrigerant fed by either direct expansion or liquid overfeed at wet conditions, dry conditions, or both.

Copies of AHRI 420–2008 may be purchased from AHRI at 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, or by going to *http://www.ahrinet.org.*

DOE also proposes to incorporate by reference specific sections from the test standard published by AHRI, titled "Standard for Performance Rating of Walk-ins," AHRI Standard 1250–2009. AHRI Standard 1250–2009 establishes definitions, test requirements, rating requirements, minimum data requirements for published ratings, operating requirements, marking and nameplate data, and conformance conditions for walk-in coolers and walk-in freezers. This testing standard applies to mechanical refrigeration equipment that consists of an integrated, single-package refrigeration unit, or as separate unit cooler and condensing unit components, where the condensing unit can be located either indoors or outdoors. Controls can be integral or can be provided by a separate party, as long as their performance is tested and certified with the listed mechanical equipment.

Copies of AHRI Standard 1250–2009 may be purchased from AHRI at 2111 Wilson Boulevard, Suite 500, Arlington, VA 22201, or by going to *http://www.ahrinet.org.*

DOE proposes to incorporate by reference ASHRAE Standard 23.1–2010, entitled "Methods of Testing for Performance Rating Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant." ASHRAE 23.1–2010 provides testing methods for rating the thermodynamic performance of positive displacement refrigerant compressors and condensing units that operate at subcritical temperatures of the refrigerant. This standard applies to all of the refrigerants listed in ASHRAE Standard 34, "Designation and Safety Classification of Refrigerants," that fall within the scope of positive displacement refrigerant compressors and condensing units that operate at subcritical temperatures of the refrigerant, which either (a) do not have liquid injection or (b) incorporate liquid injection that is achieved by compressor motor power.

Copies of ASHRAE 23.1–2010 may be purchased from ASHRAE at 1971 Tullie Circle NE., Atlanta, GA 30329, or by going to *http://www.ashrae.org.*

Finally, DOE proposes to incorporate by reference ASTM Standard C518–04, entitled "Standard Test Method for Steady-State Thermal Transmission Properties by Means of the Heat Flow Meter Apparatus." ASTM C518–04 provides a test method for measuring steady state thermal transmission through flat slab specimens using a heat flow meter apparatus, to allow determination of thermal conductance.

Copies of ASTM C518–04 may be purchased by calling ASTM Sales at 1–877–909–ASTM, or by going to *http://www.astm.org.*

V. Public Participation

A. Attendance at Public Meeting

The time, date and location of the public meeting are listed in the **DATES** and **ADDRESSES** sections at the beginning of this document. If you plan to attend the public meeting, please notify Ms. Regina Washington at (202) 586–1214 or *Regina.Washington@ee.doe.gov.*

Please note that foreign nationals visiting DOE Headquarters are subject to advance security screening procedures which require advance notice prior to attendance at the public meeting. If a foreign national wishes to participate in the public meeting, please inform DOE of this fact as soon as possible by contacting Ms. Regina Washington at (202) 586–1214 or by email: *Regina.Washington@ee.doe.gov* so that the necessary procedures can be completed.

DOE requires visitors to have laptops and other devices, such as tablets, checked upon entry into the building. Any person wishing to bring these devices into the Forrestal Building will be required to obtain a property pass. Visitors should avoid bringing these devices, or allow an extra 45 minutes to check in. Please report to the visitor's desk to have devices checked before proceeding through security.

Due to the REAL ID Act implemented by the Department of Homeland Security (DHS), there have been recent changes regarding ID requirements for individuals wishing to enter Federal buildings from specific states and U.S. territories. Driver's licenses from the following states or territory will not be accepted for building entry and one of the alternate forms of ID listed below will be required. DHS has determined that regular driver's licenses (and ID cards) from the following jurisdictions are not acceptable for entry into DOE facilities: Alaska, American Samoa, Arizona, Louisiana, Maine, Massachusetts, Minnesota, New York, Oklahoma, and Washington. Acceptable alternate forms of Photo-ID include a U.S. Passport or Passport Card; an Enhanced Driver's License or Enhanced ID-Card issued by the states of Minnesota, New York or Washington (Enhanced licenses issued by these states are clearly marked Enhanced or Enhanced Driver's License); or a military ID or other Federal government issued Photo-ID card.

In addition, you can attend the public meeting via webinar. Webinar registration information, participant instructions, and information about the capabilities available to webinar participants will be published on DOE's Web site: *https://www1.eere.energy.gov/buildings/appliance_standards/standards.aspx?productid=56&action=viewlive.* Participants are responsible for ensuring their systems are compatible with the webinar software.

B. Procedure for Submitting Prepared General Statements for Distribution

Any person who has plans to present a prepared general statement may request that copies of his or her statement be made available at the public meeting. Such persons may submit requests, along with an advance electronic copy of their statement in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format, to the appropriate address shown in the **ADDRESSES** section at the beginning of this notice. The request and advance copy of statements must be received at least one week before the public meeting and may be emailed, hand-delivered, or sent by mail. DOE prefers to receive requests and advance copies via email. Please include a telephone number to enable DOE staff to make a follow-up contact, if needed.

C. Conduct of Public Meeting

DOE will designate a DOE official to preside at the public meeting and may also use a professional facilitator to aid discussion. The meeting will not be a judicial or evidentiary-type public hearing, but DOE will conduct it in accordance with section 336 of EPCA (42 U.S.C. 6306). A court reporter will be present to record the proceedings and prepare a transcript. DOE reserves the right to schedule the order of presentations and to establish the procedures governing the conduct of the public meeting. After the public meeting and until the end of the comment period, interested parties may submit further comments on the proceedings and any aspect of the rulemaking.

The public meeting will be conducted in an informal, conference style. DOE will present summaries of comments received before the public meeting, allow time for prepared general statements by participants, and encourage all interested parties to share their views on issues affecting this rulemaking. Each participant will be allowed to make a general statement (within time limits determined by DOE), before the discussion of specific topics. DOE will permit, as time permits, other participants to comment briefly on any general statements.

At the end of all prepared statements on a topic, DOE will permit participants to clarify their statements briefly and comment on statements made by others. Participants should be prepared to answer questions by DOE and by other participants concerning these issues. DOE representatives may also ask questions of participants concerning other matters relevant to this rulemaking. The official conducting the public meeting will accept additional comments or questions from those attending, as time permits. The presiding official will announce any further procedural rules or modification of the procedures that may be needed for the proper conduct of the public meeting.

A transcript of the public meeting will be included in the docket, which can be viewed as described in the *Docket* section at the beginning of this notice. In addition, any person may buy a copy of the transcript from the transcribing reporter.

D. Submission of Comments

DOE will accept comments, data, and information regarding this proposed rule before or after the public meeting, but no later than the date provided in the **DATES** section at the beginning of this proposed rule. Interested parties may submit comments using any of the methods described in the **ADDRESSES** section at the beginning of this notice.

Submitting comments via regulations.gov. The *www.regulations.gov* Web page will require you to provide your name and contact information. Your contact information will be viewable to DOE Building Technologies staff only. Your contact information will not be publicly viewable except for your first and last names, organization name (if any), and submitter representative name (if any). If your comment is not processed properly because of technical difficulties, DOE will use this information to contact you. If DOE cannot read your comment due to technical difficulties and cannot contact you for clarification, DOE may not be able to consider your comment.

However, your contact information will be publicly viewable if you include it in the comment or in any documents attached to your comment. Any information that you do not want to be publicly viewable should not be included in your comment, nor in any document attached to your comment. Persons viewing comments will see only first and last names, organization names, correspondence containing comments, and any documents submitted with the comments.

Do not submit to *www.regulations.gov* information for which disclosure is restricted by statute, such as trade secrets and commercial or financial information (hereinafter referred to as Confidential Business Information (CBI)). Comments submitted through *www.regulations.gov* cannot be claimed as CBI. Comments received through the Web site will waive any CBI claims for the information submitted. For information on submitting CBI, see the Confidential Business Information section.

DOE processes submissions made through *www.regulations.gov* before posting. Normally, comments will be posted within a few days of being submitted. However, if large volumes of comments are being processed simultaneously, your comment may not be viewable for up to several weeks. Please keep the comment tracking number that *www.regulations.gov* provides after you have successfully uploaded your comment.

Submitting comments via email, hand delivery, or mail. Comments and documents submitted via email, hand delivery, or mail also will be posted to *www.regulations.gov.* If you do not want your personal contact information to be publicly viewable, do not include it in your comment or any accompanying documents. Instead, provide your contact information on a cover letter. Include your first and last names, email address, telephone number, and optional mailing address. The cover letter will not be publicly viewable as long as it does not include any comments

Include contact information each time you submit comments, data, documents, and other information to DOE. If you submit via mail or hand delivery, please provide all items on a CD, if feasible. It is not necessary to submit printed copies. No facsimiles (faxes) will be accepted.

Comments, data, and other information submitted to DOE electronically should be provided in PDF (preferred), Microsoft Word or Excel, WordPerfect, or text (ASCII) file format. Provide documents that are not secured, written in English and free of any defects or viruses. Documents should not contain special characters or any form of encryption and, if possible, they should carry the electronic signature of the author.

Campaign form letters. Please submit campaign form letters by the originating organization in batches of between 50 to 500 form letters per PDF or as one form letter with a list of supporters' names compiled into one or more PDFs. This reduces comment processing and posting time.

Confidential Business Information. According to 10 CFR 1004.11, any person submitting information that he or she believes to be confidential and exempt by law from public disclosure should submit via email, postal mail, or hand delivery two well-marked copies: one copy of the document marked confidential including all the information believed to be confidential, and one copy of the document marked non-confidential with the information believed to be confidential deleted. Submit these documents via email or on a CD, if feasible. DOE will make its own determination about the confidential status of the information and treat it according to its determination.

Factors of interest to DOE when evaluating requests to treat submitted information as confidential include (1) a description of the items, (2) whether and why such items are customarily treated as confidential within the industry, (3) whether the information is generally known by or available from other sources, (4) whether the information has previously been made available to others without obligation concerning its confidentiality, (5) an explanation of the competitive injury to the submitting person which would result from public disclosure, (6) when such information might lose its confidential character due to the passage of time, and (7) why disclosure of the information would be contrary to the public interest.

It is DOE's policy that all comments may be included in the public docket, without change and as received, including any personal information provided in the comments (except information deemed to be exempt from public disclosure).

E. Issues on Which DOE Seeks Comment

Although DOE welcomes comments on any aspect of this proposal, DOE is particularly interested in receiving comments and views of interested parties concerning the following issues:

(1) DOE requests comment on the proposed definitions for dedicated condensing unit and dedicated condensing refrigeration system.

(2) DOE requests comment on the proposed definition for packaged dedicated system.

(3) DOE requests comments on the proposed definitions for matched condensing unit and matched refrigeration system.

(4) DOE requests comments on the proposed definitions for indoor and outdoor condensing units.

(5) DOE requests comment on its proposal to change the "multiplex condensing" class designation to "unit cooler" and on its proposal to add a definition for "unit cooler" in the CFR, using the definition that currently is in AHRI 1250–2009.

(6) DOE requests comment on the proposed modifications to the definition of refrigeration system.

(7) DOE requests comment on the proposed definition for adaptive defrost.

(8) DOE requests comment on the definition for process cooling refrigeration system. DOE also requests data or information on any other qualities, characteristics, or features specific to the refrigeration system itself (either mentioned in this section or not) that would clearly distinguish process refrigeration from other refrigeration systems or would cause a certain process refrigeration system to be unable to meet a walk-in refrigeration system standard. DOE particularly requests data for condensing units distributed individually; in the absence of any evidence that individual condensing units designed for process refrigeration are fundamentally different from other individual condensing units, DOE will have no basis for excluding such condensing units from the scope of the standards. Further, DOE requests comment on the proposal to allow 60 days after publication of the final rule for manufacturers of process cooling refrigeration systems to attain compliance with the applicable regulations.

(9) DOE requests comment on the proposed definition for preparation room refrigeration. DOE requests comment on any other characteristics of preparation room refrigeration that (1) clearly distinguishes it from walk-in refrigeration systems and (2) would cause this equipment to be unable to meet a walk-in refrigeration standard.

(10) DOE requests comment on the proposed definition for "refrigerated storage space." DOE requests comment on whether any further clarification is needed to clearly distinguish equipment that is subject to the standard from equipment that is not.

(11) DOE requests comments on its proposal to remove from the test procedure the credit-based method for calculating the efficiency benefit of hot gas defrost.

(12) DOE requests comment on the revised representation requirements.

(13) DOE seeks comment on the proposed additions to the reporting requirements. See section V.E for a list of issues on which DOE seeks comment.

(14) DOE seeks comment on the proposed requirements for manufacturers to label their walk-in equipment and update their marketing materials for walk-in equipment to include efficiency information. DOE also seeks comment on whether it should add a requirement specifying that the permanent nameplates on doors, panels, and refrigeration systems be visible at all times, including when the component is assembled into a complete walk-in. Further, DOE asks whether these requirements are technologically and economically feasible. DOE particularly seeks data from manufacturers regarding the cost of labeling and updating marketing materials.

(15) DOE requests comment on its determination that this proposal would not introduce any changes that increase test burden or alter the measured energy use of walk-in equipment.

(16) DOE seeks input on its Initial Regulatory Flexibility Analysis from businesses that would be affected by this rulemaking and will consider comments received in the development of any final rule.

VI. Approval of the Office of the Secretary

The Secretary of Energy has approved publication of this proposed rule.

List of Subjects

10 CFR Part 429

Administrative practice and procedure, Confidential business information, Energy conservation, Reporting and recordkeeping requirements.

10 CFR Part 431

Administrative practice and procedure, Confidential business information, Energy conservation test procedures, Incorporation by reference, and Reporting and recordkeeping requirements.

Issued in Washington, DC, on July 29, 2016.

Kathleen B. Hogan,

Deputy Assistant Secretary for Energy Efficiency, Energy Efficiency and Renewable Energy.

For the reasons stated in the preamble, DOE is proposing to amend parts 429 and 431 of chapter II of title 10, Code of Federal Regulations as set forth below:

PART 429—CERTIFICATION, COMPLIANCE, AND ENFORCEMENT FOR CONSUMER PRODUCTS AND COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 1. The authority citation for part 429 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 2. Section 429.12 is amended by revising paragraph (b)(6) to read as follows:

§ 429.12 General requirements applicable to certification reports.

* * * * *

(b) * * *

(6) For each brand, the basic model number and the manufacturer's individual model number(s) in that basic model with the following exceptions: For external power supplies that are certified based on design families, the design family model number and the individual manufacturer's model numbers covered by that design family must be submitted for each brand. For distribution transformers, the basic model number or kVA grouping model number (depending on the certification method) for each brand must be submitted. For commercial HVAC, WH, and refrigeration equipment, an individual manufacturer model number may be identified as a "private model number" if it meets the requirements of § 429.7(b).

* * * * *

■ 3. Section 429.53 is revised to read as follows:

§ 429.53 Walk-in coolers and walk-in freezers.

(a) *Determination of represented value.* (1) The requirements of § 429.11 are applicable to walk-in coolers and walk-in freezers; and

(2) For each basic model of walk-in cooler and walk-in freezer refrigeration system, the annual walk-in energy factor (AWEF) must be determined either by testing, in accordance with § 431.304 of this chapter and the provisions of this section, or by application of an AEDM that meets the requirements of § 429.70 and the provisions of this section.

(i) *Applicable test procedure.* If the AWEF is determined by testing, refer to the following for the appropriate test procedure to use:

(A) *Unit cooler test procedure.* For unit coolers tested alone, use the test procedure in 10 CFR part 431, subpart R, appendix C. Follow the general testing provisions in appendix C, sections 3.1 and 3.2, and the product-specific provisions in appendix C, section 3.3.

(B) *Dedicated condensing unit test procedure.* For dedicated condensing units tested alone, use the test procedure in 10 CFR part 431, subpart R, appendix C. Follow the general testing provisions in appendix C, sections 3.1 and 3.2, and the product-specific provisions in appendix C, section 3.4.

(C) *Packaged dedicated system test procedure.* For packaged dedicated systems, use the test procedure in 10 CFR part 431, subpart R, appendix C. Follow the general testing provisions in appendix C, sections 3.1 and 3.2, and the product-specific provisions in appendix C, section 3.3.

(D) *Matched refrigeration system test procedure.* For matched refrigeration systems, use the test procedure in 10 CFR part 431, subpart R, appendix C. Follow the general testing provisions in appendix C, sections 3.1 and 3.2, and the product-specific provisions in appendix C, section 3.3. It is not necessary to rate a matched refrigeration system if the constituent unit cooler(s) and dedicated condensing unit have been tested and rated as specified paragraphs (a)(2)(i)(A) and (B), respectively. However, if a manufacturer wishes to represent the efficiency of the matched refrigeration system as distinct from the efficiency of either constituent component, or if the manufacturer cannot rate one or both of the constituent components using the specified method, the manufacturer must test and certify the matched refrigeration system as specified in this paragraph (a)(2)(i)(D).

(ii) *Units to be tested.* (A) If the represented value for a given refrigeration system basic model is determined through testing, the general requirements of § 429.11 apply; and

(B) For each basic model, a sample of sufficient size shall be randomly selected and tested to ensure that any represented value of AWEF or other measure of energy efficiency of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

(*1*) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

And $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the i^{th} sample, or,

(*2*) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with n-1 degrees of freedom (from appendix A to subpart B).

(C) The represented value of net capacity shall be the average of the capacities measured for the sample selected.

(iii) *Alternative efficiency determination methods.* In lieu of testing, a represented value of AWEF for a basic model of a walk-in cooler or freezer refrigeration system must be determined through the application of an AEDM pursuant to the requirements of § 429.70 and the provisions of this section, where:

(A) Any represented value of AWEF or other measure of energy efficiency of a basic model for which consumers would favor higher values shall be less than or equal to the output of the AEDM and greater than or equal to the Federal standard for that basic model.

(B) The represented value of net capacity must be the net capacity simulated by the AEDM.

(3) For each basic model of walk-in cooler and walk-in freezer panels, display doors, and non-display doors, the R-value and/or energy consumption must be determined by testing, in accordance with § 431.304 of this chapter and the provisions of this section.

(i) *Applicable test procedure.* Refer to the following for the appropriate test procedure:

(A) *Display door test procedure.* For determining the energy consumption and rated surface area in square feet, use the test procedure in 10 CFR part 431, subpart R, appendix A.

(B) *Non-display door test procedure.* For determining the energy consumption and rated surface area in square feet, use the test procedure in 10 CFR part 431, subpart R, appendix A. For determining the R-value, use the test procedure in 10 CFR part 431, subpart R, appendix B.

(C) *Panel test procedure.* For determining the R-value, use the test procedure in 10 CFR part 431, subpart R, appendix B.

(ii) *Units to be tested.* (A) The general requirements of § 429.11 apply; and

(B) For each basic model, a sample of sufficient size shall be randomly selected and tested to ensure that—

(*1*) Any represented value of door energy consumption or other measure of energy use of a basic model for which consumers would favor lower values shall be greater than or equal to the higher of:

(*i*) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

And $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the i^{th} sample, or,

(*ii*) The upper 95 percent confidence limit (UCL) of the true mean divided by 1.05, where:

$$UCL = \bar{x} + t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with n-1 degrees of freedom (from appendix A to subpart B).

(*2*) Any represented value of R-value or other measure of energy efficiency of a basic model for which consumers would favor higher values shall be less than or equal to the lower of:

(*i*) The mean of the sample, where:

$$\bar{x} = \frac{1}{n}\sum_{i=1}^{n} x_i$$

And $\bar{x}$ is the sample mean; n is the number of samples; and x_i is the i^{th} sample, or,

(*ii*) The lower 95 percent confidence limit (LCL) of the true mean divided by 0.95, where:

$$LCL = \bar{x} - t_{0.95}\left(\frac{s}{\sqrt{n}}\right)$$

And $\bar{x}$ is the sample mean; s is the sample standard deviation; n is the number of samples; and $t_{0.95}$ is the t statistic for a 95% one-tailed confidence interval with n-1 degrees of freedom (from appendix A to subpart B).

(b) *Certification reports.* (1) The requirements of § 429.12 are applicable to manufacturers of walk-in cooler and walk-in freezer panels, doors, and refrigeration systems, and;

(2) Pursuant to § 429.12(b)(13), a certification report must include the following public product-specific information:

(i) *For doors:* The door type, R-value of the door insulation, and a declaration that the manufacturer has incorporated the applicable design requirements. In addition, for those walk-in coolers and walk-in freezers with transparent reach-in doors and windows: The glass type of the doors and windows (*e.g.,* double-pane with heat reflective treatment, triple-pane glass with gas fill), and the power draw of the antisweat heater in watts per square foot of door opening.

(ii) *For walk-in cooler and walk-in freezer panels:* The R-value of the insulation.

(iii) *For walk-in cooler and walk-in freezer refrigeration systems:* The motor's purpose (*i.e.,* evaporator fan motor or condenser fan motor), the horsepower, and a declaration that the manufacturer has incorporated the applicable design requirements.

(3) Pursuant to § 429.12(b)(13), starting on June 5, 2017, a certification report must include the following public product-specific information in addition to the information listed in paragraph (b)(2) of this section:

(i) *For walk-in cooler and walk-in freezer doors:* The door energy consumption and rated surface area in square feet.

(ii) For refrigeration systems that are medium-temperature dedicated condensing units, medium-temperature packaged dedicated systems, or medium-temperature matched systems: The refrigeration system AWEF, net capacity, and the configuration tested for certification (*e.g.,* condensing unit only, unit cooler only, or matched pair).

(4) Pursuant to § 429.12(b)(13), starting on June 5, 2017, a certification report must include the following product-specific information in addition to the information listed in paragraphs (b)(2) and (3) of this section: For doors: The rated power of each light, heater wire, and/or other electricity consuming device associated with each basic model of display and non-display door; and whether such device(s) has a timer, control system, or other demand-based control reducing the device's power consumption.

(5) Starting on [COMPLIANCE DATE OF FINAL RULE FOR UPDATED REFRIGERATION STANDARDS], a certification report must include the following public product-specific information in addition to the information listed in paragraph (b)(2) of this section:

(i) For refrigeration systems that are low-temperature dedicated condensing units, low-temperature matched systems, or medium and low-temperature unit coolers: The refrigeration system AWEF, net capacity, and the configuration tested for certification (*e.g.,* condensing unit only, unit cooler only, or matched pair).

■ 4. Section 429.110 is amended by revising paragraph (e)(2) to read as follows:

§ 429.110 Enforcement testing.

* * * * *

(e) * * *

(2) For automatic commercial ice makers; commercial refrigerators, freezers, and refrigerator-freezers; refrigerated bottled or canned vending machines; commercial air conditioners and heat pumps; commercial packaged boilers; commercial warm air furnaces; commercial water heating equipment; and walk-in cooler and freezer refrigeration systems, DOE will use an initial sample size of not more than four units and follow the sampling plans in appendix B of this subpart (Sampling Plan for Enforcement Testing of Covered Equipment and Certain Low-Volume Covered Products).

* * * * *

■ 4. Section 429.134 is amended by adding paragraph (l) to read as follows:

§ 429.134 Product-specific enforcement provisions.

* * * * *

(l) *Walk-in coolers and walk-in freezers.* (1) If DOE determines that a basic model of a panel, door, or refrigeration system for walk-in coolers or walk-in freezers fails to meet an applicable energy conservation standard, then the manufacturer of that basic model is responsible for the noncompliance with the applicable standard. If DOE determines that a complete walk-in cooler or walk-in freezer or component thereof fails to meet an applicable energy conservation standard, then the manufacturer of that walk-in cooler or walk-in freezer is responsible for the noncompliance with the applicable standard, except that the manufacturer of a complete walk-in cooler or walk-in freezer is not responsible either for the use of components that were certified and labeled as compliant by another party that are later found to be noncompliant.

(2) *Verification of refrigeration system net capacity.* The net capacity of the refrigeration system basic model will be measured pursuant to the test requirements of 10 CFR part 431, subpart R, appendix C for each unit tested. The results of the measurement(s) will be averaged and compared to the value of net capacity certified by the manufacturer. The certified net capacity will be considered valid only if the average measured net capacity is within five percent of the certified net capacity.

(i) If the certified net capacity is found to be valid, the certified net capacity will be used as the basis for calculating the AWEF of the basic model.

(ii) If the certified refrigeration capacity is found to be invalid, the average measured refrigeration capacity will serve as the basis for calculating the annual energy consumption for the basic model.

(3) *Verification of door surface area.* The surface area of a display door or non-display door basic model will be measured pursuant to the requirements of 10 CFR part 431, subpart R, appendix A for each unit tested. The results of the measurement(s) will be averaged and compared to the value of the surface area certified by the manufacturer. The certified surface area will be considered valid only if the average measured surface area is within one percent of the certified surface area.

(i) If the certified surface area is found to be valid, the certified surface area will be used as the basis for calculating the maximum energy consumption (kWh/day) of the basic model.

(ii) If the certified surface area is found to be invalid, the average measured surface area will serve as the basis for calculating the maximum energy consumption (kWh/day) of the basic model.

(4) For each basic model of walk-in cooler and freezer door, DOE will calculate the door's energy consumption using the power listed on the nameplate of each electricity consuming device shipped with the door. If an electricity consuming device shipped with a walk-in door does not have a nameplate or such nameplate does not list the device's power, then DOE will use the device's "rated power" included in the door's certification report.

PART 431—ENERGY EFFICIENCY PROGRAM FOR CERTAIN COMMERCIAL AND INDUSTRIAL EQUIPMENT

■ 5. The authority citation for part 431 continues to read as follows:

Authority: 42 U.S.C. 6291–6317; 28 U.S.C. 2461 note.

■ 6. Section 431.302 is amended by:

■ a. Adding in alphabetical order, definitions for "Adaptive defrost," "Dedicated condensing unit," "Dedicated condensing refrigeration system," "Indoor dedicated condensing refrigeration system," "Matched condensing unit," "Matched refrigeration system," "Outdoor dedicated condensing refrigeration system," "Packaged dedicated system," "Preparation room refrigeration," "Refrigerated storage space," "Unit cooler", and "Walk-in process cooling refrigeration system"; and

■ b. Revising the definition of "refrigeration system";

The revision and additions read as follows:

§ 431.302 Definitions concerning walk-in coolers and walk-in freezers.

Adaptive defrost means a defrost control system that reduces defrost frequency by initiating defrosts or adjusting the number of defrosts per day in response to operating conditions (*e.g.,* moisture levels in the refrigerated space, measurements that represent coil frost load) rather than initiating defrost strictly based on compressor run time or clock time.

* * * * *

Dedicated condensing unit means a positive displacement condensing unit that is part of a refrigeration system (as defined in 10 CFR 431.302) and is an assembly that

(1) Includes 1 or more compressors, a condenser, and one refrigeration circuit; and

(2) Is designed to serve one refrigerated load.

Dedicated condensing refrigeration system means either:

(1) A dedicated condensing unit;

(b) A packaged dedicated system; or

(3) A matched refrigeration system.

* * * * *

Indoor dedicated condensing refrigeration system means a dedicated condensing refrigeration system that is not an outdoor dedicated refrigeration system.

* * * * *

Matched condensing unit means a dedicated condensing unit that is distributed in commerce with one or more unit cooler(s) specified by the condensing unit manufacturer.

Matched refrigeration system (also called matched pair) means a refrigeration system including the matched condensing unit and the one or more unit coolers with which it is distributed in commerce.

Outdoor dedicated condensing refrigeration system means a dedicated condensing unit, packaged dedicated system, or matched refrigeration system in which the assembly (including the compressor(s) and condenser) is encased and the system is capable of maintaining a net capacity at the 35 °F outdoor temperature condition that is no less than 65 percent of the net capacity measured at the 95 °F outdoor temperature condition for a period of no less than one hour.

Packaged dedicated system means a refrigeration system (as defined in 10 CFR 431.302) that is a single-package assembly that includes one or more compressors, a condenser, a means for forced circulation of refrigerated air, and elements by which heat is transferred from air to refrigerant, without any element external to the system imposing resistance to flow of the refrigerated air.

* * * * *

Preparation room refrigeration means a unit cooler that is designed for use in a room occupied by personnel who are preparing food and that is characterized by low outlet air velocity, evaporator temperature between 30 and 55 degrees Fahrenheit, and electric or hot gas defrost.

* * * * *

Refrigerated storage space means a space held at refrigerated (as defined in 10 CFR 431.302) temperatures.

* * * * *

Refrigeration system means the mechanism (including all controls and other components integral to the system's operation) used to create the refrigerated environment in the interior of a walk-in cooler or freezer, consisting of:

(1) A dedicated condensing refrigeration system (as defined in 10 CFR 431.302); or

(2) A unit cooler.

* * * * *

Unit cooler means an assembly, including means for forced air circulation and elements by which heat is transferred from air to refrigerant without any element external to the cooler imposing air resistance.

* * * * *

Walk-in process cooling refrigeration system means a refrigeration system that is used exclusively for cooling food or other substances from one temperature to another. The basic model of such a system must either:

(1) Be distributed in commerce with an enclosure consisting of panels and door(s) such that the assembled product has a refrigerating capacity of at least 100 Btu/h per cubic foot of enclosed internal volume; or

(2) Be a unit cooler having an evaporator coil that is at least four-and-one-half (4.5) feet in height and whose height is at least one-and-one-half (1.5) times the width.

■ 7. Section 431.303 is amended by:

■ a. Redesignating paragraph (b)(1) as (b)(2), and adding new paragraph (b)(1);

■ b. Revising newly redesignated paragraph (b)(2), by removing "§ 431.304", and adding in its place, "§ 431.304 and appendix C to subpart R of part 431.

■ c. Redesignating paragraphs (c) and (d) as paragraphs (d) and (e), respectively, and adding new paragraph (c);

■ d. Revising newly redesignated paragraph (d)(1), by removing "appendix A to subpart R of part 431" and adding in its place, "appendix B to subpart R of part 431".

The revisions and addition read as follows:

§ 431.303 Materials incorporated by reference.

* * * * *

(b) * * *

(1) ANSI/AHRI 420–2008, ("AHRI 420–2008"), "Performance Rating of Forced-Circulation Free-Delivery Unit Coolers for Refrigeration," Copyright 2008, IBR approved for appendix C to subpart R of part 431.

* * * * *

(c) *ASHRAE.* The American Society of Heating, Refrigerating, and Air-Conditioning Engineers, Inc., 1971 Tullie Circle NE., Atlanta, GA 30329, or *http://www.ashrae.org/.*

(1) ANSI/ASHRAE Standard 23.1–2010, ("ASHRAE 23.1–2010"), "Methods of Testing for Rating the Performance of Positive Displacement Refrigerant Compressors and Condensing Units that Operate at Subcritical Temperatures of the Refrigerant," Copyright 2010, IBR approved for appendix C to subpart R of part 431.

(2) [Reserved].

* * * * *

■ 8. Section 431.304 is amended by revising paragraph (b) and removing paragraph (c) to read as follows:

§ 431.304 Uniform test method for the measurement of energy consumption of walk-in coolers and walk-in freezers.

* * * * *

(b) Determine the energy efficiency and/or energy consumption of the specified walk-in cooler and walk-in freezer components by conducting the appropriate test procedure as follows:

(1) Determine the U-factor, conduction load, and energy use of walk-in cooler and walk-in freezer display panels by conducting the test procedure set forth in appendix A to this subpart.

(2) Determine the energy use of walk-in cooler and walk-in freezer display doors and non-display doors by conducting the test procedure set forth in appendix A to this subpart.

(3) Determine the R-value of walk-in cooler and walk-in freezer non-display panels and non-display doors by conducting the test procedure set forth in appendix B to this subpart.

(4) Determine the AWEF and net capacity of walk-in cooler and walk-in freezer refrigeration systems by conducting the test procedure set forth in appendix C to this subpart.

■ 9. Section 431.305 is added to read as follows:

§ 431.305 Walk-in coolers and walk-in freezers labeling requirements.

(a) Panel nameplate—(1) Required information. The permanent nameplate of a walk-in cooler or walk-in freezer panel for which standards are prescribed in § 431.306 must be marked clearly with the following information:

(i) The rated R-value;

(ii) The panel brand;

(iii) The panel model number;

(iv) The date of manufacture of the panel; and

(v) The statement, "This panel is designed and certified for use in walk-in cooler and freezer applications."

(2) Display of required information. All orientation, spacing, type sizes, typefaces, and line widths to display this required information must be the same as or similar to the display of the other performance data included on the panel's permanent nameplate. The R-value, as appropriate to a given panel model, must be identified in the form "R-value __." The model number must be in one of the following forms: "Model __" or "Model number __" or "Model No. __."

(b) Door nameplate—(1) Required information. The permanent nameplate of a walk-in cooler or walk-in freezer door for which standards are prescribed in § 431.306 must be marked clearly with the following information:

(i) The rated energy consumption;

(ii) The door brand;

(iii) The door model number;

(iv) The date of manufacture of the door; and

(v) The statement, "This door is designed and certified for use in walk-in cooler and freezer applications."

(2) Display of required information. All orientation, spacing, type sizes, typefaces, and line widths to display this required information must be the same as or similar to the display of the other performance data included on the door's permanent nameplate. The energy consumption, as appropriate to a given door model, must be identified in the form "EC __." The model number must be in one of the following forms: "Model __" or "Model number __" or "Model No. __."

(c) Refrigeration system nameplate—(1) Required information. The permanent nameplate of a walk-in cooler or walk-in freezer refrigeration system for which standards are prescribed in § 431.306 must be marked clearly with the following information:

(i) The annual walk-in energy factor;

(ii) The refrigeration system brand;

(iii) The refrigeration system model number;

(iv) The date of manufacture of the refrigeration system; and

(v) The statement, "This refrigeration system is designed and certified for use in walk-in cooler and freezer applications."

(2) Process cooling refrigeration systems. The permanent nameplate of a process cooling refrigeration system (as defined in § 431.302) must be marked clearly with the following information:

(i) The refrigeration system brand;

(ii) The refrigeration system model number;

(iii) The date of manufacture of the refrigeration system; and

(iv) The statement, "This refrigeration system is designed only for use in walk-in cooler and freezer process cooling refrigeration applications."

(2) Display of required information. All orientation, spacing, type sizes, typefaces, and line widths to display this required information must be the same as or similar to the display of the other performance data included on the refrigeration system's permanent nameplate. The annual walk-in energy factor, as appropriate to a given refrigeration system model, must be identified in the form "AWEF __." The model number must be in one of the following forms: "Model __" or "Model number __" or "Model No. __."

(d) Disclosure of efficiency information in marketing materials. (1) The same information that must appear on a walk-in cooler or walk-in freezer component's permanent nameplate pursuant to paragraph (a)(1) of this section, must also be prominently displayed:

(i) On each page of a catalog that lists the component; and

(ii) In other materials used to market the component.

■ 10. Appendix A to subpart R of part 431 is amended by:

■ a. Removing and reserving sections 3.2 and 3.3;

■ b. Revising section 3.4;

■ c. Redesignating sections 3.5 and 3.6 as sections 3.6 and 3.7.

■ d. Adding new section 3.5;

■ e. Revising newly redesignated section 3.6; and

■ f. Revising Table A.1.

The revisions and additions read as follows:

Appendix A to Subpart R of Part 431—Uniform Test Method for the Measurement of Energy Consumption of the Components of Envelopes of Walk-In Coolers and Walk-In Freezers

* * * * *

3.2 [Reserved]

3.3 [Reserved]

3.4 *Surface area* means the area of the surface of the walk-in component that would be external to the walk-in cooler or walk-in freezer as appropriate.

3.5 *Rated power* means the electricity consuming device's power as specified on the device's nameplate. If the device does not have a nameplate or such nameplate does not list the device's power, then the rated power must be read from the device's product data sheet.

3.6 *Rating conditions* means, unless explicitly stated otherwise, all conditions shown in Table A.1 of this section.

TABLE A.1—TEMPERATURE CONDITIONS

Internal Temperatures (cooled space within the envelope)	
Cooler Dry Bulb Temperature	35 °F.
Freezer Dry Bulb Temperature	−10 °F.
External Temperatures (space external to the envelope)	
Freezer and Cooler Dry Bulb Temperatures	75 °F.

* * * * *

■ 11. Adding appendices B and C to subpart R of part 431 to read as follows:

Appendix B to Subpart R of Part 431—Uniform Test Method for the Measurement of R-Value for Envelope Components of Walk-In Coolers and Walk-in Freezers

1.0 Scope

This appendix covers the test requirements used to measure the R-value of non-display panels and non-display doors of a walk-in cooler or walk-in freezer.

2.0 Definitions

The definitions contained in § 431.302 apply to this appendix.

3.0 Additional Definitions

3.1 *Edge region* means a region of the panel that is wide enough to encompass any framing members. If the panel contains framing members (*e.g.* a wood frame) then the width of the edge region must be as wide as any framing member plus an additional 2 in. ±0.25 in.

4.0 Test Methods, Measurements, and Calculations

4.1 The R value shall be the 1/K factor multiplied by the thickness of the panel.

4.2 The K factor shall be based on ASTM C518 (incorporated by reference; see § 431.303).

4.3 For calculating the R value for freezers, the K factor of the foam at 20 ±1 degrees Fahrenheit (average foam temperature) shall be used. Test results from a test sample 1 ±0.1-inches in thickness may be used to determine the R value of panels with various foam thickness as long as the foam is of the same final chemical form.

4.4 For calculating the R value for coolers, the K factor of the foam at 55 ±1 degrees Fahrenheit (average foam temperature) shall be used. Test results from a test sample 1 ±0.1-inches in thickness may be used to determine the R value of panels with various foam thickness as long as the foam is of the same final chemical form.

4.5 Foam shall be tested after it is produced in its final chemical form. For foam produced inside of a panel ("foam-in-place"), "final chemical form" means the foam is cured as intended and ready for use as a finished panel. For foam produced as board stock (typically polystyrene), "final chemical form" means after extrusion and ready for assembly into a panel or after assembly into a panel. Foam from foam-in-place panels must not include any structural members or non-foam materials. Foam produced as board stock may be tested prior to its incorporation into a final panel. A test sample 1 ±0.1-inches in thickness must be taken from the center of a panel and any protective skins or facers must be removed. A high-speed band-saw and a meat slicer are two types of recommended cutting tools. Hot wire cutters or other heated tools must not be used for cutting foam test samples. The two surfaces of the test sample that will contact the hot plate assemblies (as defined in ASTM C518 (incorporated by reference, see § 431.303)) must both maintain ±0.03 inches flatness tolerance and also maintain parallelism with respect to one another within ±0.03 inches. Testing must be completed within 24 hours of samples being cut for testing.

4.6 Internal non-foam member and/or edge regions shall not be considered when testing in accordance with ASTM C518.

4.7 For panels consisting of two or more layers of dissimilar insulating materials (excluding facers or protective skins), test each material as described in sections 4.1 through 4.6 of this appendix. For a panel with N layers of insulating material, the overall R-Value shall be calculated as follows:

$$R_{panel} = \sum_{i=1}^{N} \frac{t_i}{k_i}$$

Where:

k_i is the k factor of the ith material as measured by ASTM C518, (incorporated by reference, see § 431.303)

t_i is the thickness of the ith material that appears in the panel, and

N is the total number of material layers that appears in the panel.

Appendix C to Subpart R of Part 431—Uniform Test Method for the Measurement of Net Capacity and AWEF of Walk-In Coolers and Walk-in Freezer Refrigeration Systems

1.0 Scope

This appendix covers the test requirements used to determine the net capacity and the AWEF of the refrigeration system of a walk-in cooler or walk-in freezer.

2.0 Definitions

The definitions contained in § 431.302 and AHRI 1250–2009 (incorporated by reference; see § 431.303) apply to this appendix. When definitions in standards incorporated by reference are in conflict or when they are in conflict with this section, the hierarchy of precedence shall be in the following order: § 431.302, AHRI 1250–2009 (incorporated by reference; see § 431.303), and then either AHRI 420–2008 (incorporated by reference; see § 431.303) for unit coolers or ASHRAE 23.1–2010 (incorporated by reference; see § 431.303) for dedicated condensing units.

3.0 Test Methods, Measurements, and Calculations

Determine the Annual Walk-in Energy Factor (AWEF) and net capacity of walk-in cooler and walk-in freezer refrigeration systems by conducting the test procedure set forth in AHRI 1250–2009 (incorporated by reference; see § 431.303), with the modifications to that test procedure provided in this section. When standards that are incorporated by reference are in conflict or when they are in conflict with this section, the hierarchy of precedence shall be in the following order: § 431.302, AHRI 1250–2009 (incorporated by reference; see § 431.303), and then either AHRI 420–2008 (incorporated by reference; see § 431.303) or ASHRAE 23.1–2010 (incorporated by reference; see § 431.303).

3.1. *General modifications:* Test Conditions and Tolerances.

When conducting testing in accordance with AHRI 1250–2009 (incorporated by reference; see § 431.303), the following modifications must be made.

3.1.1. In Table 1, Instrumentation Accuracy, refrigerant temperature measurements shall have a tolerance of ±0.5 F for unit cooler in/out, ±1.0 F for all other temperature measurements.

3.1.2. In Table 2, Test Operating and Test Condition Tolerances for Steady-State Test, electrical power frequency shall have a Test Condition Tolerance of 1 percent.

3.1.3. In Table 2, the Test Operating Tolerances and Test Condition Tolerances for Air Leaving Temperatures shall be deleted.

3.1.4. In Tables 2 through 14, the Test Condition Outdoor Wet Bulb Temperature requirement and its associated tolerance apply only to units with evaporative cooling.

3.1.5. Tables 15 and 16 shall be modified to read as follows:

TABLE 15—REFRIGERATOR UNIT COOLER

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	35	<50				Compressor Off	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A.	35	<50	25	105	9	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler.
Refrigeration Capacity Suction B.	35	<50	20	105	9	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler.

Note: Superheat to be set according to equipment specification in equipment or installation manual. If no superheat specification is given, a default superheat value of 6.5 °F shall be used. The superheat setting used in the test shall be reported as part of the standard rating.

TABLE 16—FREEZER UNIT COOLER

Test description	Unit cooler air entering dry-bulb, °F	Unit cooler air entering relative humidity, %	Saturated suction temp, °F	Liquid inlet saturation temp, °F	Liquid inlet subcooling temp, °F	Compressor capacity	Test objective
Off Cycle Fan Power	−10	<50				Compressor Off	Measure fan input power during compressor off cycle.
Refrigeration Capacity Suction A.	−10	<50	−20	105	9	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler.
Refrigeration Capacity Suction B.	−10	<50	−26	105	9	Compressor On	Determine Net Refrigeration Capacity of Unit Cooler.
Defrost	−10	Various				Compressor Off	Test according to Appendix C Section C11.

Note: Superheat to be set according to equipment specification in equipment or installation manual. If no superheat specification is given, a default superheat value of 6.5 °F shall be used. The superheat setting used in the test shall be reported as part of the standard rating.

3.2. *General Modifications:* Methods of Testing.

When conducting testing in accordance with appendix C of AHRI 1250–2009 (incorporated by reference; see § 431.303), the following modifications must be made.

3.2.1. In appendix C, section C3.1.6, any refrigerant temperature measurements upstream and downstream of the unit cooler may use sheathed sensors immersed in the flowing refrigerant instead of thermometer wells.

3.2.2. It is not necessary to perform composition analysis of refrigerant (appendix C, section C3.3.6) or refrigerant oil concentration testing (appendix C, section C3.4.6).

3.2.3. In appendix C, section C3.4.5, for verification of sub-cooling downstream of mass flow meters, only the sight glass and a temperature sensor located on the tube surface under the insulation are required.

3.2.4. In appendix C, section C3.5, regarding unit cooler fan power measurements, for a given motor winding configuration, the total power input shall be measured at the highest nameplate voltage. For three-phase power, voltage imbalances shall be no more than 2 percent from phase to phase.

3.2.5. In the test setup (appendix C, section C8.3), the liquid line and suction line shall be constructed of pipes of the manufacturer-specified size. The pipe lines shall be insulated with a minimum total thermal resistance equivalent to ½-inch thick insulation having a flat-surface R-Value of 3.7 ft^2 – °F-hr/Btu per inch or greater. Flow meters need not be insulated but must not be in contact with the floor. The lengths of the connected liquid line and suction line shall be 25 feet +/− 3 inches, not including the requisite flow meters, each. Of this length, no more than 15 feet shall be in the conditioned space. Where there are multiple branches of piping, the maximum length of piping applies to each branch individually as opposed to the total length of the piping.

3.3. *Matched systems, packaged dedicated systems, and unit coolers tested alone:* Use the test method in AHRI 1250–2009 (incorporated by reference; see § 431.303), appendix C as the method of test for matched refrigeration systems, packaged dedicated systems, or unit coolers tested alone, with the following modifications:

3.3.1. For unit coolers tested alone, use test procedures described in AHRI 1250–2009 (incorporated by reference; see § 431.303) for testing unit coolers for use in mix-match system ratings, except that for the test conditions in Tables 15 and 16, use the Suction A saturation condition test points only. Also for unit coolers tested alone, use calculations in section 7.9 to determine AWEF and net capacity described in AHRI 1250–2009 (incorporated by reference; see § 431.303) for unit coolers matched to parallel rack systems.

3.3.2. In appendix C, section C.13, the version of AHRI Standard 420 used for test methods, requirements, and procedures shall be ANSI/AHRI 420–2008 (incorporated by reference; see § 431.303).

3.3.3. Use appendix C, section C10 of AHRI 1250–2009 for off-cycle evaporator fan testing, with the exception that evaporator fan controls using periodic stir cycles shall be adjusted so that the greater of a 50% duty cycle (rather than a 25% duty cycle) or the manufacturer default is used for measuring off-cycle fan energy. For variable-speed controls, the greater of 50% fan speed (rather than 25% fan speed) or the manufacturer's default fan speed shall be used for measuring off-cycle fan energy.

3.3.4. Use appendix C, section C11 of AHRI 1250–2009 for defrost testing. The Frost Load Condition Defrost Test (C11.1.1) is optional.

3.3.4.1. If the frost load condition defrost test is performed:

3.3.4.1.1 Operate the unit cooler at the dry coil conditions as specified in appendix C, section C11.1 to obtain dry coil defrost energy, DF_d, in W-h.

3.3.4.1.2 Operate the unit cooler at the frost load conditions as specified in appendix C, sections C11.1 and C11.1.1 to obtain frosted coil defrost energy, DF_f, in W-h.

3.3.4.1.3 The number of defrosts per day, N_{DF}, shall be calculated from the time interval between successive defrosts at the frost load conditions.

3.3.4.1.4 Use appendix C, equations C13 and C14 in section C11.3 to calculate, respectively, the daily average defrost energy, DF, in W-h and the daily contribution of the load attributed to defrost Q_{DF} in Btu.

3.3.4.1.5 The defrost adequacy requirements in appendix C, section C11.3 shall apply.

3.3.4.2. If the frost load test is not performed:

3.3.4.2.1 Operate the unit cooler at the dry coil conditions as specified in appendix C, section C11.1 to obtain dry coil defrost energy, DF_d, in W-h.

3.3.4.2.2 The frost load defrost energy, DF_f, in W-h shall be equal to 1.05 multiplied by the dry coil energy consumption, DF_d, measured using the dry coil condition test in appendix C, section C11.1.

3.3.4.2.3 The number of defrosts per day N_{DF} used in subsequent calculations shall be 4.

3.3.4.2.4 Use appendix C, equation C13 in section C11.3 to calculate the daily average defrost energy, DF, in W-h.

3.3.4.2.5 The daily contribution of the load attributed to defrost Q_{DF} in Btu shall be calculated as follows:

$$Q_{DF} = 0.95 \times 3.412\ \text{Btu/W-h} \times \frac{2.05\ \times DF_d}{2} \times 4$$

Where:

DF_d = the defrost energy, in W-h, measured at the dry coil condition

3.3.5. If a unit has adaptive defrost:

3.3.5.1. When testing to certify to the energy conservation standards in 10 CFR 431.306, do not perform the optional test for adaptive or demand defrost in appendix C, section C11.2.

3.3.5.2. When determining the represented value of the calculated benefit for the inclusion of adaptive defrost, conduct the optional test for adaptive or demand defrost in appendix C, section C11.2 to establish the maximum time interval allowed between dry coil defrosts. Then, calculate N_{DF} (the number of defrosts per day) by averaging the measured time in hours between successive defrosts for the dry coil condition with the time in hours between successive defrosts for the frosted coil condition, and dividing 24 by this average time. The measured time between defrosts cannot be greater than 24 hours. (The time between successive defrosts for the frosted coil condition is found as specified in section 3.3.4 of this appendix: that is, if the optional frosted coil test was performed, the time between successive defrosts for the frosted coil condition is found by performing the frosted coil test as specified in section 3.3.4.1; and if the optional frosted coil test was not performed, the time between successive defrosts for the frosted coil condition shall be set to 4 as specified in section 3.3.4.2.) Use this new value of N_{DF} in subsequent calculations.

3.3.6. For matched refrigeration systems, calculate the AWEF using the calculations in AHRI 1250–2009 (incorporated by reference; see § 431.303), section 7.4, 7.5, 7.6, or 7.7, as applicable. In section 7.6, use the following equations in place of equations 67 and 83, respectively:

Equation 67:

$$b = \frac{EER_{SS}{}^{k=1}(t_{IH}) - EER_{SS}{}^{k=2}(t_{IIH}) - d \times \left[EER_{SS}{}^{k=1}(t_{IH}) - EER_{SS}{}^{k=i}(t_{VH})\right]}{t_{IH} - t_{IIH} - d \times [t_{IH} - t_{VH}]}$$

Equation 83:

$$b = \frac{EER_{SS}{}^{k=1}(t_{IL}) - EER_{SS}{}^{k=2}(t_{IIL}) - d \times \left[EER_{SS}{}^{k=1}(t_{IL}) - EER_{SS}{}^{k=i}(t_{VL})\right]}{t_{IL} - t_{IIL} - d \times [t_{IL} - t_{VL}]}$$

3.3.7. For unit coolers tested alone, calculate the AWEF and net capacity using the calculations in AHRI 1250–2009, (incorporated by reference; see § 431.303), section 7.9. If the unit cooler has variable-speed evaporator fans that vary fan speed in response to load, then:

3.3.7.1. When testing to certify compliance with the energy conservation standards in § 431.306, fans shall operate at full speed during on-cycle operation. Do not conduct the calculations in AHRI 1250–2009 section 7.9.3. Instead, use AHRI 1250–2009 section 7.9.2 to determine the system's AWEF.

3.3.7.2. When calculating the benefit for the inclusion of variable-speed evaporator fans that modulate fan speed in response to load for the purposes of making representations of efficiency, use AHRI 1250–2009 section 7.9.3 to determine the system AWEF.

3.4. *Dedicated condensing units that are not matched for testing and are not packaged dedicated systems.*

3.4.1. Refer to appendix C, section C.12 of AHRI 1250–2009 (incorporated by reference; see § 431.303), for the method of test for dedicated condensing units. The version of ASHRAE Standard 23 used for test methods, requirements, and procedures shall be ANSI/ASHRAE Standard 23.1–2010 (incorporated by reference; see § 431.303). When applying this test method, use the applicable test method modifications listed in sections 3.1 and 3.2 of this appendix. For the test conditions in AHRI 1250–2009 Tables 11, 12, 13, and 14, use the Suction A condition test points only.

3.4.2. Calculate the AWEF and net capacity for dedicated condensing units using the calculations in AHRI 1250–2009 (incorporated by reference; see 10 CFR 431.303) section 7.8. Use the following modifications to the calculations in lieu of unit cooler test data:

3.4.2.1. For purposes of calculating enthalpy leaving the unit cooler as part of the calculating gross capacity, the saturated refrigerant temperature at the evaporator coil exit, T_{evap}, shall be 25 °F for medium-temperature systems (coolers) and -20 °F for low-temperature systems (freezers).

3.4.2.2. The on-cycle evaporator fan power in watts, $EF_{comp,on}$, shall be calculated as follows:

For medium-temperature systems (coolers), $EF_{comp,on} = 0.013 \times q_{mix,cd}$

For low-temperature systems (freezers), $EF_{comp,on} = 0.016 \times q_{mix,cd}$

Where:

$q_{mix,cd}$ is the gross cooling capacity of the system in Btu/h, found by a single test at the Capacity A, Suction A condition for outdoor units and the Suction A condition for indoor units.

3.4.2.3. The off-cycle evaporator fan power in watts, $EF_{comp,off}$, shall be calculated as follows:

$EF_{comp,off} = 0.2 \times EF_{comp,on}$

Where:

$EF_{comp,on}$ is the on-cycle evaporator fan power in watts.

3.4.2.4. The daily defrost energy use in watt-hours, DF, shall be calculated as follows:

For medium-temperature systems (coolers), $DF = 0$

For low-temperature systems (freezers), $DF = 8.5 \times 10^{-3} \times q_{mix,cd}{}^{1.27} \times N_{DF}$

Where:

$q_{mix,cd}$ is the gross cooling capacity of the system in Btu/h, found by a single test at the Capacity A, Suction A condition for outdoor units and the Suction A condition for indoor units, and

N_{DF} is the number of defrosts per day, equal to 4.

3.4.2.5. The daily defrost heat load contribution in Btu, Q_{DF}, shall be calculated as follows:

For medium-temperature systems (coolers), $Q_{DF} = 0$

For low-temperature systems (freezers), $Q_{DF} = 0.95 \times DF \times 3.412$

Where:

DF is the daily defrost energy use in watt-hours.

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Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 20, 25, 170, et al.
Substances Generally Recognized as Safe; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 20, 25, 170, 184, 186, and 570

[Docket No. FDA–1997–N–0020 (formerly 97N–0103)]

RIN 0910–AH15

Substances Generally Recognized as Safe

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA or we) is issuing a final rule that amends and clarifies the criteria in our regulations for when the use of a substance in food for humans or animals is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) because the substance is generally recognized as safe (GRAS) under the conditions of its intended use. We also are amending our regulations to replace the voluntary GRAS affirmation petition process with a voluntary notification procedure under which any person may notify us of a conclusion that a substance is GRAS under the conditions of its intended use. The clarified criteria for GRAS status should help stakeholders draw more informed conclusions about whether the intended conditions of use of a substance in food for humans or animals complies with the FD&C Act, and the notification procedure will enable stakeholders to be aware of whether we have questioned the basis of a conclusion of GRAS status.

DATES: This rule is effective October 17, 2016. Submit comments on information collection issues under the Paperwork Reduction Act of 1995 by October 17, 2016 (see section XXIX, the "Paperwork Reduction Act of 1995" section of this document).

ADDRESSES: To ensure that comments on the information collection are received, the Office of Management and Budget (OMB) recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0342 and titled "Substances Generally Recognized as Safe." Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: *Regarding substances that would be used in human food:* Paulette M. Gaynor, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740, 240–402–1192. *Regarding substances that would be used in animal food:* Geoffrey K. Wong, Center for Veterinary Medicine (HFV–224), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 240–402–5838.

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Executive Summary

Purpose and Coverage of the Rule

Although we have premarket review authority over food additives, a food manufacturer can intentionally add a substance to human food or animal food without our premarket review or approval if the substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use (GRAS). Since the 1970s, we have had regulations clarifying the statutory provision for eligibility for classification as GRAS. We also have had regulations governing a procedure for any person to voluntarily submit to us a petition asking us to affirm the GRAS status of a substance under the conditions of its intended use, and for us to engage in an intensive rulemaking process in response to that petition. Experience has shown that our regulations need further clarification to help stakeholders understand when a substance is eligible for classification as GRAS in human food or animal food under the conditions of its intended use. Experience also has shown that streamlining our evaluation of conclusions of GRAS status will enable us to evaluate more, and higher priority, substances. We are issuing this final rule to amend and clarify the criteria in our regulations for when a substance is GRAS under the conditions of its intended use in human food or animal food, and to replace the voluntary administrative procedure for petitioning us to affirm the GRAS status of a use of a substance in human food or animal food with a voluntary administrative procedure for notifying us about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food.

Summary of the Major Provisions of the Rule

The final rule clarifies the criteria for the use of a substance to be eligible for classification as GRAS and establishes a new administrative procedure for any person to notify us of the basis for a conclusion that a substance is GRAS under the conditions of its intended use. With respect to criteria for eligibility for classification as GRAS, in the final rule we clarify that:

- A substance cannot be classified as GRAS under the conditions of its intended use if the available data and information do not satisfy the safety standard for a food additive under the FD&C Act;
- General recognition of safety requires common knowledge, throughout the expert scientific community knowledgeable about the safety of substances directly or indirectly added to food, that there is a reasonable certainty that the substance is not harmful under the conditions of its intended use;
- "Common knowledge" can be based on either "scientific procedures" or on experience based on common use of a substance in food prior to January 1, 1958; and
- General recognition of safety through scientific procedures must be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

With respect to the procedure for submitting a GRAS notice, we provide:

- Definitions for certain terms, including amendment, GRAS notice, notified substance, notifier, qualified expert, supplement, we/our/us, and you/your;
- A clear statement of the opportunity for any person to submit a GRAS notice;
- Information on available formats (electronic and paper) and where to send a GRAS notice;
- What data and other information may be incorporated into a GRAS notice;
- General provisions applicable to a GRAS notice;
- Specific information you must provide in your GRAS notice, including:
  - Signed statements and a certification (Part 1);
  - The identity, method of manufacture, specifications, and physical or technical effect of the notified substance (Part 2);
  - Dietary exposure (Part 3);
  - Self-limiting levels of use, in circumstances where the amount of the notified substance that can be added to human food or animal food is limited because the food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical (Part 4);
  - The history of consumption of the substance for food use by a significant number of consumers (or animals in the case of animal food) prior to January 1, 1958, if a conclusion of GRAS status is based on common use of the substance in food prior to 1958 (Part 5);
  - A narrative that provides the basis for your conclusion of GRAS status, including why the scientific data, information, methods, and principles

described in the notice provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use (Part 6); and

○ A list of the data and information that you discuss in the narrative of your GRAS notice, specifying which of these data and information are generally available, and which of these data and information are not generally available (Part 7); and

- Process for you to submit an amendment to your GRAS notice; and
- Process for you to request that we cease to evaluate your GRAS notice.

With respect to our administration of a GRAS notice, we specify:

- Information about how we will file a GRAS notice, respond to it, and send subsequent correspondence about it;
- Our commitment to respond within 180 days of filing of a GRAS notice, with a potential to extend our response timeframe by another 90 days;
- Our procedures in the event the intended conditions of use of the notified substance include use in a product subject to regulation by the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA); and
- Provisions governing the public disclosure of a GRAS notice, including the actions we take to make some information regarding a GRAS notice readily accessible to the public.

As of the effective date of the final rule, we will close the docket for any pending GRAS affirmation petition. The petitioner may incorporate the applicable petition into a new GRAS notice.

Costs and Benefits

The final rule eliminates the petition process to affirm that a substance is GRAS under the conditions of its intended use and replaces that petition process with a GRAS notification procedure. We estimate that over 10 years with a 7 percent discount rate, the present value of the total costs of the final rule range from $0.9 million to $3.3 million; with a 3 percent discount rate, the present value of the total costs range from $0.9 million to $3.4 million. The annualized costs of the rule range from $0.1 million to $0.4 million with a 7 percent discount rate and range from $0.1 million to $0.5 million with a 3 percent discount rate. We do not quantify the benefits of the final rule, but assume that firms will only participate in the GRAS notification procedure when they expect to receive a non-negative private benefit. The GRAS notification procedure will allow us to complete our evaluation within the timelines specified in the final rule. The following table includes a summary of the benefits and costs of the final rule.

SUMMARY OF BENEFITS AND COSTS OF THE FINAL RULE

Total benefits	Present value of total costs with 7 percent discount rate ($ mil)	Present value of total costs with 3 percent discount rate ($ mil)	Total annualized costs over 10 years with 7 percent discount rate ($ mil)	Total annualized costs over 10 years with 3 percent discount rate ($ mil)
Not estimated	$0.9 to $3.3	$0.9 to $3.4	$0.1 to $0.4	$0.1 to $0.5.

TABLE OF ABBREVIATIONS AND ACRONYMS

Abbreviation/acronym	What it means
1958 amendment	1958 Food Additives Amendment to the Federal Food, Drug, and Cosmetic Act.
AAFCO	Association of American Feed Control Officials.
Affected petitioner	Any person who had submitted a pending petition.
BATF	Bureau of Alcohol, Tobacco, and Firearms.
CFSAN	Center for Food Safety and Applied Nutrition.
CVM	Center for Veterinary Medicine.
EPA	U.S. Environmental Protection Agency.
FDA	U.S. Food and Drug Administration.
FDAMA	1997 Food and Drug Administration Modernization Act.
FD&C Act	Federal Food, Drug, and Cosmetic Act.
FOIA	Freedom of Information Act.
FSIS	Food Safety and Inspection Service of the U.S. Department of Agriculture.
GAO	Government Accountability Office.
GRAS	Generally Recognized as Safe.
JECFA	Joint Expert Committee on Food Additives.
MOU	Memorandum of Understanding.
N/A	Not Applicable.
OMB	Office of Management and Budget.
Pdf	Portable document format.
Pending petition	A filed GRAS affirmation petition that is pending on the date that the petition process is replaced with a notification procedure.
PHO	Partially hydrogenated oil.
PRA	Paperwork Reduction Act.
TTB	Alcohol and Tobacco Tax and Trade Bureau.
USDA	U.S. Department of Agriculture.

I. Introduction

A. History of FDA's Approach to the GRAS Provision of the FD&C Act

In 1958, in response to public concern about the increased use of chemicals in foods and food processing and with the support of the food industry, Congress enacted the Food Additives Amendment (the 1958 amendment) to the FD&C Act. The basic thrust of the 1958 amendment was to require that, before a substance could be used in food, its sponsor demonstrate the safety of the substance to FDA, and that we establish a regulation prescribing the conditions under which the substance may be safely used. The 1958 amendment defined the terms "food additive" (21 U.S.C. 321(s)) and "unsafe food additive" (21 U.S.C. 348(a)), established a premarket approval process for food additives (21 U.S.C. 348(b) through (g)), and amended the food adulteration provisions of the FD&C Act to deem adulterated any food that is, or bears or contains, any food additive that is unsafe within the meaning of 21 U.S.C. 348 (see 21 U.S.C. 342(a)(2)(C)).

Congress recognized that, under this scheme, the safety of a food additive could not be established with absolute certainty, and thus provided for a science-based safety standard that requires sponsors of food additives to demonstrate to a reasonable certainty that no harm will result from the intended use of an additive (Ref. 1). We have incorporated this safety standard into our regulations for food additives and GRAS substances (§ 170.3(i)) (21 CFR 170.3(i)). (We note that although this rule addresses substances intended for use in animal food as well as substances intended for use in human food, in this introduction we describe the history of the our GRAS regulations from the perspective of human food only.) If we find an additive to be safe, based ordinarily on data submitted by the sponsor to us in a food additive petition, we promulgate a regulation specifying the conditions under which the additive may be safely used.

In enacting the 1958 amendment, Congress recognized that many substances intentionally added to food would not require a formal premarket review by FDA to assure their safety, either because their safety had been established by a long history of use in food or by virtue of the nature of the substance, its customary or projected conditions of use, and the information generally available to scientists about the substance. Congress thus adopted, in section 201(s) of the FD&C Act (21 U.S.C. 321(s)), a two-step definition of "food additive." The first step broadly includes any substance, the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of food. The second step, however, excludes from the definition of "food additive" substances that are generally recognized, among experts qualified by scientific training and experience to evaluate their safety ("qualified experts"), as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or through experience based on common use in food) to be safe under the conditions of their intended use. Importantly, under section 201(s) of the FD&C Act, it is the use of a substance, rather than the substance itself, that is eligible for GRAS status. It is on the basis of the GRAS provision within the food additive definition that many substances (such as vinegar, vegetable oil, baking powder, and many spices, flavors, gums, and preservatives) are lawfully marketed today without a food additive regulation. Under the 1958 amendment, a substance that is GRAS for a particular use may be marketed for that use without our review and approval. However, when a use of a substance does not qualify for GRAS status or other exceptions provided under section 201(s) of the FD&C Act, that use of the substance is a food additive use subject to the premarket approval mandated by the FD&C Act. In such circumstances, we can take enforcement action to stop distribution of the food substance and foods containing it on the grounds that such foods are or contain an unlawful food additive.

Shortly after passage of the 1958 amendment, we clarified the regulatory status of a multitude of food substances that were used in food prior to 1958 and amended our regulations to include a list of food substances that, when used for the purposes indicated and in accordance with good manufacturing practice, are GRAS. This list was incorporated into our regulations as § 121.101(d) (21 CFR 121.101(d)) (now part 182 (21 CFR part 182)) (24 FR 9368; November 20, 1959). As part of that rulemaking, however, we acknowledged that it would be impracticable to list all substances that are GRAS for their intended use (§ 121.101(a); current § 182.1(a)).

Section 121.101(d) became commonly referred to as "the GRAS list." We added other categories of substances (*e.g.*, spices, seasonings, and flavorings) to the GRAS list in subsequent rulemakings (25 FR 404, January 19, 1960; and 26 FR 3991, May 9, 1961).

Many substances that were considered GRAS by the food industry were not included in our GRAS list. Under the 1958 amendment, a substance that is GRAS under the conditions of its intended use may be marketed for that use without Agency review and approval. Nonetheless, as a practical matter, manufacturers who concluded on their own initiative that use of a substance qualified for GRAS status frequently decided to obtain our opinion on whether their conclusion was justified. Many manufacturers wrote to us and requested an "opinion letter," in which Agency officials would render an informal opinion on the GRAS status of use of a substance. Although convenient and expedient, these opinion letters were often available only to the requestor. Moreover, these opinion letters were not binding on us even at the time they were issued and letters issued before April 9, 1970, were in fact revoked (21 CFR 170.6; 35 FR 5810; April 9, 1970).

In 1969 (34 FR 17063; October 21, 1969), we deleted various cyclamate salts, a family of nonnutritive sweeteners, from the GRAS list because they were implicated in the formation of bladder tumors in rats (Ref. 2). In response to the concerns raised by the new information on cyclamates, then-President Nixon directed us to reexamine the safety of GRAS substances (Ref. 3), and we announced that we were conducting a comprehensive study of substances presumed to be GRAS (35 FR 18623; December 8, 1970). The purpose of the study was to evaluate, by contemporary standards, the available safety information regarding substances presumed to be GRAS and to promulgate each item in a new (*i.e.*, affirmed) GRAS list, a food additive regulation, or an interim food additive regulation pending completion of additional studies.

In the notice announcing the comprehensive review of presumed GRAS substances, we proposed criteria that could be used to establish whether these substances should be listed as GRAS, become the subject of a food additive regulation, or be listed in an interim food additive regulation pending completion of additional studies (35 FR 18623). These criteria were incorporated into our regulations as § 121.3 (precursor of current § 170.30) (36 FR 12093; June 25, 1971).

We made a second announcement that we were conducting a study of presumed GRAS substances (36 FR 20546; October 23, 1971) and subsequently instituted a rulemaking to establish procedures that we could use, on our own initiative, to affirm the GRAS status of substances that were the subject of that review and were found to satisfy the criteria established in § 121.3 (proposed rule, 37 FR 6207, March 25, 1972; final rule, 37 FR 25705, December 2, 1972). These procedures were subsequently codified at § 170.35(a) and (b). Because the GRAS review did not cover all GRAS substances (*e.g.*, it did not cover many substances that were marketed based on a manufacturer's independent conclusion of GRAS status), that rulemaking included a mechanism (the GRAS affirmation petition process; § 170.35(c)) whereby an individual could petition us to review the GRAS status of substances not being considered as part of our GRAS review. We codified our affirmations of GRAS status in current parts 184 and 186 (21 CFR parts 184 and 186).

In 1974, we proposed to clarify the criteria for GRAS status, the differences between GRAS status and food additive status, and the procedures being used to conduct the current review of food substances (39 FR 34194; September 23, 1974). The final regulations based on this proposal amended § 121.3 (now § 170.30) to distinguish a conclusion of GRAS status through scientific procedures (§ 170.30(b)) from a conclusion of GRAS status through experience based on common use in food (§ 170.30(c)) (41 FR 53600; December 7, 1976). Those final regulations also established definitions for "common use in food" (now § 170.3(f)) and "scientific procedures" (now § 170.3(h)). We subsequently added criteria (§ 170.30(c)(2)) for the determination of GRAS status through experience based on common use in food when that use occurred exclusively or primarily outside of the United States (53 FR 16544; May 10, 1988).

To the extent that a person elected to submit a GRAS affirmation petition, the GRAS affirmation process could facilitate awareness, by us as well as the domestic and international food industry, of independent conclusions of GRAS status. However, the GRAS affirmation petition process involved the resource-intensive rulemaking process. In the **Federal Register** of April 17, 1997 (62 FR 18938; the proposed rule), we proposed to: (1) Clarify the criteria for eligibility for classification as GRAS; and (2) replace the GRAS affirmation petition process with a notification procedure whereby any person may notify us of a conclusion that a particular use of a substance is GRAS. We explained that we would evaluate whether the notice provides a sufficient basis for a GRAS conclusion and whether information in the notice or otherwise available to us raises issues that lead us to question whether use of the substance is GRAS. We would respond to the notifier in writing and could advise the notifier that we had identified a problem with the notice. Although information in a notice would be publicly available consistent with the Freedom of Information Act (FOIA), we would make readily accessible to the public a basic description the notified substance, the conditions of its intended use, and the statutory basis for GRAS status (*i.e.,* through scientific procedures or through experience based on common use in food), as well as our response to the notice. In 2010, we reopened the comment period for the proposed rule to update comments and to solicit comment on specific issues (75 FR 81536, December 28, 2010; the 2010 notice). (See section II.D for additional information about this reopening of the comment period).

In the proposed rule, we invited interested persons to notify us about their conclusions of GRAS status as described in the proposed rule (62 FR 18938 at 18954; the "Interim Pilot program"). Our Center for Food Safety and Applied Nutrition (CFSAN) filed its first GRAS notice in 1998 and has filed 614 GRAS notices as of December 31, 2015. Our Center for Veterinary Medicine (CVM) established its Interim Pilot program more recently (75 FR 31800, June 4, 2010) and filed its first GRAS notice in December 2010. As of December 31, 2015, CVM has filed 18 GRAS notices.

B. Report by the Government Accountability Office and How We Are Addressing Its Recommendations

From 2008 to 2010, the Government Accountability Office (GAO) conducted a study related to ingredients used in human food on the basis of the GRAS provision in section 201(s) of the FD&C Act. In 2010, GAO issued a report (Ref. 4; the GAO report) that included a number of recommendations for FDA. For example, the GAO report recommended that we finalize the proposed rule to establish a notification program for GRAS substances, strive to minimize the potential for conflict of interest on "GRAS panels," issue guidance on how to document GRAS conclusions, and obtain more information about the use of engineered nanomaterials. (As we note in section VI.B, this document uses the term "GRAS panel" to mean a panel of individuals convened for the purpose of evaluating whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in food.) Consistent with the recommendations in the GAO report, this document finalizes the GRAS notification procedure as requested by GAO. It also announces our intent to issue guidance in the near future to: (1) Provide recommendations regarding the use of a "GRAS panel," including the potential for conflict of interest; and (2) remind the food industry that the same standards apply to a conclusion of GRAS status regardless of whether the conclusion is submitted to us as a GRAS notice or is not submitted to us. (See Response 125, Response 128, and Response 129).

In 2012, we made available a draft guidance entitled "Draft Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients That Are Color Additives" (Ref. 5) (77 FR 24722, April 25, 2012). We finalized this guidance in 2014 (Ref. 6) (79 FR 36533, June 27, 2014). The guidance includes recommendations for assessing the effect of a significant manufacturing process change (including the use of nanotechnology) on the safety and regulatory status of substances used in human food, including those that are GRAS. In this guidance, we stated that, at present, for nanotechnology applications in food substances, there are questions related to the technical evidence of safety as well as the general recognition of that safety, that are likely to be sufficient to warrant formal premarket review and approval by FDA, rather than to satisfy criteria for GRAS status. In addition, in 2011, we made available a draft guidance entitled "Considering Whether an FDA-Regulated Product Involves the Application of Nanotechnology" (Ref. 7) (76 FR 34715, June 14, 2011). We finalized this guidance in 2014 (Ref. 8) (June 27, 2014, 79 FR 36534), which describes our thinking on determining whether FDA-regulated products involve the application of nanotechnology.

C. Issues Regarding the Legal and Regulatory Framework for Substances Added to Food

The GAO report discussed issues fundamental to the legal and regulatory framework for our oversight of the safety of substances added to food, such as the voluntary nature of the GRAS affirmation petition process and the proposed GRAS notification procedure. In light of these issues, the GAO report recommended that we ask any company evaluating whether a substance is GRAS under the conditions of its intended use to provide us with basic information about any conclusion of GRAS status (Ref. 4). Some comments to this rulemaking raise similar issues. For example, some comments address the voluntary nature of the GRAS notification procedure or assert that we have implied legal authority to require that companies notify us of a conclusion of GRAS status (see Comment 1 and Comment 28). Some comments ask us to require companies to maintain active and accurate listings for all GRAS substances, not just those that are the subject of a GRAS regulation or a GRAS notice, in a public database (see Comment 3). Some comments ask us to require certain postmarket submissions of exposure and safety data related to all GRAS substances, to require submissions for conclusions of GRAS status that predate the final rule, and to require any notifier who "withdraws" a GRAS notice or receives an "insufficient basis letter" to notify us about any use of that substance (see Comment 30). One comment asks us to exclude uses of "novel" substances from consideration for eligibility for classification as GRAS (see Comment 19).

Some comments discuss an industry practice of convening a "GRAS panel" of "qualified experts" to provide an opinion on whether a company's evaluation of the available data and information support a conclusion that a substance is safe under the conditions of its intended use, and express concern that such a "GRAS panel" may base its opinion partly on confidential data and information that are provided to the GRAS panel, but not provided to us in a submitted GRAS notice (see Comment 10 through Comment 14, Comment 69, and Comment 78).

Some comments express concern that the GRAS notification procedure would be viewed as a "fast-track" option that would tempt a company that should submit a food additive petition to submit a GRAS notice instead (see Comment 32). A published critique of the GRAS notification procedure (Ref. 9) likewise expresses concern that industry is simply using the GRAS notification procedure as an alternative to the food additive petition process, contrasting the number of food additive petitions filed in recent years with the number of GRAS notices filed in recent years. This report also expresses concern that there are an indeterminate—but not insignificant—number of industry conclusions of GRAS status that are not the subject of a GRAS notice to FDA.

In this document, we respond to such comments in the context of our proposed revisions to the criteria for eligibility for classification as GRAS and our proposal to replace one voluntary administrative procedure, *i.e.*, the GRAS affirmation petition process, with a different voluntary administrative procedure, *i.e.*, the GRAS notification procedure. (See Response 1, Response 3, Response 10 through Response 14, Response 19, Response 28, Response 30, Response 32, Response 69, and Response 78). As we discuss in Response 28, the broader issues raised by these comments about the legal and regulatory framework for our oversight of the safety of substances added to food are outside the scope of this rulemaking. Thus, this final rule does not address the possibility that we might enhance our oversight through additional rulemaking or other actions based on our current legal authority. Nonetheless, we will continue to consider the broader issues raised by these comments and take further action as appropriate under our existing authority through future rulemaking. Importantly, however, this final rule *does* establish uniform criteria for describing the basis for a conclusion that a substance is GRAS under the conditions of its intended use, and those uniform criteria apply to all conclusions of GRAS status, not just conclusions of GRAS status that are submitted to us as a GRAS notice. As discussed in Response 129, we are issuing a guidance directed to any person who evaluates whether the available data and information regarding the safety of a substance under the conditions of its intended use satisfy GRAS criteria. The purpose of the guidance is to: (1) Remind such persons of their responsibilities under the FD&C Act regarding a conclusion of GRAS status, regardless of whether the conclusion of GRAS status is submitted to us as a GRAS notice; and (2) refer such persons to key resources, such as those discussed in Response 128, for evaluating the safety of the substance under the conditions of its intended use and for evaluating whether the available data and information regarding safety satisfy the criteria for eligibility for classification as GRAS in § 170.30.

D. Recent FDA Actions Related to GRAS Criteria

In the following paragraphs, we describe two examples of steps we have taken to address concerns about the safety of certain substances marketed under the GRAS provision. The first example is partially hydrogenated oils (PHOs), which are the primary dietary source of industrially produced *trans* fatty acids, or *trans* fat. The second example is certain uses of caffeine.

Although we had not listed the most commonly used PHOs in either part 182 or part 184, they had been used in food for many years based on conclusions of GRAS status by industry. In a notice published in the **Federal Register** of November 8, 2013 (78 FR 67169), we described new scientific evidence and the findings of expert scientific panels regarding *trans* fat and requested comments and scientific data and information on our tentative determination that PHOs are not GRAS for any use in food based on current scientific evidence establishing the health risks associated with the consumption of *trans* fat. In the **Federal Register** of June 17, 2015 (80 FR 34650), we issued a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food.

The GRAS list in part 182 includes the use of caffeine in cola-type beverages at a maximum level of 0.02 percent (§ 182.1180). In 2010, we issued four warning letters regarding the use of caffeine under markedly different conditions of use than the use listed in § 182.1180, *i.e.*, the use of caffeine as an added ingredient in alcoholic beverages (Ref. 10 through Ref. 13). In our letters, we stated that, based on the publicly available literature, a number of qualified experts have concerns about the safety of caffeinated alcoholic beverages. We described these concerns, citing published literature. We further stated that FDA is not aware of data or other information to establish the safety of caffeine as used in these products. We therefore informed the companies who were marketing these caffeinated alcoholic beverages that caffeine, as used in the companies' products, is an unsafe food additive, and therefore the products are adulterated under section 402(a)(2)(C) of the FD&C Act (21 U.S.C. 342(a)(2)(C)). (The Alcohol and Tobacco Tax and Trade Bureau (TTB) also notified the four companies that if we deem their caffeinated alcohol beverage products adulterated under the FD&C Act, TTB would consider them to be mislabeled under the Federal Alcohol Administration Act, making it a violation for industry members to sell or ship the products in interstate or foreign commerce (Ref. 14).) The companies subsequently ceased distribution of these products.

In recent years, other food and beverage products containing caffeine as an added substance have been introduced into the marketplace, including so-called "energy drinks" that are frequently marketed for their stimulant properties. When there are new uses of an added food substance without FDA's premarket engagement, presumably because a manufacturer has concluded that such a use is GRAS, we must react to the new uses after they emerge. In such cases, it can be challenging for FDA to accurately assess consumption patterns and intake levels and to determine whether those new uses are safe and lawful in light of all of the available safety data. FDA has engaged with the National Academies of Science (Ref. 15), trade associations, and other industry representatives, some of whom are conducting a systematic review on the health effects associated with the consumption of caffeine (Ref. 16 and Ref. 17).

E. Moving Forward Under This Final Rule

We believe that our filing of more than 600 GRAS notices for substances used in human food is evidence that the substitution of a GRAS notification procedure for the GRAS affirmation petition process has benefits for consumers, FDA, the regulated industry, and other stakeholders. We have increased our awareness of the composition of the nation's food supply and the dietary exposure to GRAS substances, which helps us to ensure the safe use of substances added to food. The ongoing submission of GRAS notices provides evidence that our response to a GRAS notice can support the marketing of a food substance by the regulated industry. Notified substances include substances that are intended to address food safety problems (*e.g.,* antimicrobial substances and substances intended to reduce acrylamide formation) and public health issues (*e.g.,* substances that would reduce levels of sodium chloride in food). In addition, the letters we issue responding to GRAS notices demonstrate that we inform notifiers of any scientific or regulatory issues that call into question a notifier's conclusion of GRAS status, and stakeholders have ready access to those letters. As discussed in Response 81, we intend to increase the transparency of our response letters when a notifier asks us to cease to evaluate a GRAS notice.

In the years since we published the proposed rule, we have taken important public health actions with respect to substances used in food on the basis of the GRAS provision of the FD&C Act. For example, we recently announced an initiative to establish voluntary short-term and long-term goals for sodium reduction in a variety of identified categories of foods to address the excessive intake of sodium in the current population and promote improvements in public health (81 FR 35363, June 2, 2016). In addition, we recently held a public meeting in which we invited public comment on what should be included, changed, or even excluded from our guidance entitled "Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients" (79 FR 64603, October 30, 2014); that guidance is intended to help interested parties understand our expectations regarding how to determine which toxicity studies are appropriate and regarding the design, conduct, and reporting of the results of toxicity studies and applies to assessing the safety of GRAS substances. As discussed in section I.D, we also have taken key postmarket actions such as issuing a declaratory order announcing our final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food, as well as issuing warning letters regarding the use of caffeine as an added ingredient in alcoholic beverages.

For reasons such as those discussed in this section, and after fully considering comments submitted to this rulemaking, this rule announces that we are replacing the former GRAS affirmation petition process with a GRAS notification procedure.

We strongly encourage any company considering the addition of a substance to any food on the basis of a conclusion of GRAS status to contact us and follow the available procedures for FDA oversight of such decisions. As we move forward to implement the GRAS notification procedure that is the subject of this rulemaking, we intend to continue to closely monitor and assess the ramifications of the use of substances without food additive approval or evaluation by FDA through the GRAS notification procedure. We intend to take action as appropriate, such as we did in the case of PHOs and caffeinated alcoholic beverages, particularly when the available data and information raise a safety concern about the use of a substance.

We advise any company that intends to market a food substance on the basis of an independent conclusion of GRAS status (*i.e.,* a conclusion of GRAS status that would remain with the proponent of the conclusion rather than be submitted to us as a GRAS notice) to carefully consider whether this use fully satisfies the criteria for eligibility for classification as GRAS and to carefully review the discussions in this document relevant to those criteria. Fundamental to all conclusions of GRAS status is the criterion that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (see § 170.30(a)). In addition, the criteria for eligibility for classification as GRAS through scientific procedures require that general recognition of safety through scientific procedures be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles (§ 170.30(b)). Although general recognition of safety through scientific procedures may be corroborated by the application of unpublished scientific data, information, or methods (§ 170.30(b)), to satisfy GRAS criteria qualified experts must be able to conclude that the substance is not harmful under the conditions of its intended use without access to "corroborative" information (see, *e.g.,* Response 9). For example, as discussed in Response 69 there could be no basis for a conclusion of GRAS status if trade secret information (or other non-public information) is necessary for qualified experts to reach a conclusion that the notified substance is safe under the conditions of its intended use.

We also advise any company who intends to market a food substance on the basis of an independent GRAS conclusion that relies, in whole or in part, on the opinion of a specially convened "GRAS panel" to carefully review the discussions in this document regarding whether and how the opinion of a GRAS panel can support an independent conclusion of GRAS status. For example, as discussed in Response 10 and Response 11 whether a published "GRAS panel" opinion that discusses data and information that are available to the members of the GRAS panel, but not generally available to qualified experts, could support an independent conclusion of GRAS status would depend on factors such as whether that publication includes details similar to details that would be included in a publication in the primary scientific literature; the subject matter expertise of the members of the GRAS panel; and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use. For example, a published GRAS panel opinion that includes a very general statement that a study was conducted and reported no adverse findings would not suffice to make the study "generally available" as required by the criteria for eligibility for classification as GRAS and would merely be a generally available opinion about data and information that are not generally available. As another example, a "GRAS panel" opinion published by scientists without expertise appropriate to address the applicable safety questions could not provide evidence that the conclusions in the publication are "generally accepted.'' Unless both criteria, *i.e.,* ''generally available'' as well as ''generally accepted'', are satisfied, there would be no basis for a conclusion of GRAS status.

II. Background

A. The Proposed Rule

We proposed to: (1) Clarify the criteria for eligibility for classification as GRAS; and (2) replace the GRAS affirmation petition process with a notification procedure through which any interested person may notify us of a determination that a particular use of a substance is GRAS (62 FR 18938). In the proposed rule, we:

- Discussed the 1958 amendment, including judicial decisions bearing on GRAS criteria and the burden on the proponent of a conclusion of GRAS status to show that there is a consensus of expert opinion regarding the safety of the use of the substance (62 FR 18938 at 18939);
- Described the history of our approach to the GRAS provision, including: (1) A GRAS list, first established in 1959, in which we clarified the regulatory status of a multitude of food substances that were used in food prior to 1958; (2) opinion letters in which Agency officials rendered an informal, non-binding opinion on the GRAS status of a use of a substance; (3) an FDA-initiated GRAS review to evaluate the available safety information regarding substances presumed to be GRAS; and (4) GRAS criteria and the GRAS affirmation petition process (62 FR 18938 at 18939 to 18940);
- Discussed ''elements of the GRAS standard,'' in which we distinguished the ''technical element'' of the GRAS standard (*i.e.,* safety) from the ''common knowledge element'' of the GRAS standard (*i.e.,* general recognition) (62 FR 18938 at 18940 to 18941);
- Proposed the submission requirements for the GRAS notification procedure, including: (1) A ''GRAS exemption claim,'' in which a notifier would take responsibility for a GRAS determination; (2) information about the identity of the notified substance; (3) information about any self-limiting levels of use; and (4) a comprehensive discussion of the basis for the GRAS determination (proposed §§ 170.36 (c) and 570.36(c));
- Proposed what we would do when we received a GRAS notice, including: (1) Acknowledge receipt of the GRAS notice; (2) evaluate whether the notice provides a sufficient basis for a GRAS determination and respond to the notifier in writing; (3) make readily accessible to the public the notice's ''GRAS exemption claim'' and our response to the notice; and (4) disclose other releasable information in a notice in accordance with our regulations, in part 20 (21 CFR part 20), implementing the FOIA (proposed §§ 170.36 (d) through (f) and 570.36(d) through (f)); and
- Proposed to: (1) Convert any GRAS affirmation petition that was pending on the effective date of the rule establishing the notification procedure to a GRAS notice; and (2) require the petitioner to submit an amendment to the converted petition to satisfy the procedural requirements of the GRAS notification procedure (proposed §§ 170.36(g) and 570.36(g)).

We requested comments on the proposed rule by July 16, 1997.

B. Interim Pilot Program

In the proposed rule, we invited interested persons who determine that a use of a substance is GRAS to notify us of those determinations as described in the proposed rule (62 FR 18938 at 18954). We explained that we would administer the notices as described in the proposed rule (*i.e.,* we would acknowledge receipt of the notice, respond in writing to the notifier, and make publicly accessible a copy of all ''GRAS exemption claims'' and our response). Although we would make a good faith effort to respond within the proposed 90-day timeframe, we would not be bound by such a timeframe. We stated that we would determine whether our experience in administering such notices suggests modifications to the proposed procedure.

CFSAN received its first GRAS notice in 1998. CFSAN wrote a memorandum documenting its experience in evaluating GRAS notices during the period 1998–2009 (Ref. 18, ''CFSAN's 2010 experience document'') and added that memorandum to the docket for this rulemaking in 2010. Unless we say otherwise, the discussions in this document referring to FDA's experience during the Interim Pilot program refer to CFSAN's experience.

During the Interim Pilot program, CFSAN's response to a GRAS notice fell into three categories as shown in table 1 in this document. We refer to these categories of response throughout this document. Table 1 in CFSAN's 2010 experience document shows the category of response for CFSAN's GRAS notices that came to closure by December 31, 2009. CFSAN has now written an updated memorandum showing the category of response for CFSAN's GRAS notices that came to closure by December 31, 2015 (Ref. 19).

TABLE 1—CATEGORIES OF LETTERS RESPONDING TO A GRAS NOTICE DURING THE INTERIM PILOT PROGRAM

Category of response letter	Typical text of the response
''No questions letter''	Based on the information provided by the notifier, as well as other information available to FDA, the Agency has no questions at this time regarding the notifier's conclusion that the notified substance is GRAS under the intended conditions of use. The Agency has not, however, made its own determination regarding the GRAS status of the subject use of the notified substance. As always, it is the continuing responsibility of the notifier to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.
''Insufficient basis letter''	FDA has evaluated the information that the notifier discusses in its GRAS notice as well as other data and information that are available to us. The notice does not provide a sufficient basis for a determination that the notified substance is GRAS under the conditions of its intended use.
''Cease to evaluate letter''	In correspondence dated [month, day, year], you asked that we cease to evaluate your notice. We ceased to evaluate your GRAS notice, effective the date we received your correspondence.

In this document, we frequently cite CFSAN's experience during the Interim Pilot program when responding to comments asking us to clarify how we intend to administer various provisions of the rule, as well as state our intent to continue the applicable practice in the future, because this experience is relevant to our administration of the GRAS notification program. Nonetheless, we intend to adapt our practices, consistent with the provisions of this rule, as circumstances warrant and as necessary to administer the GRAS notification program consistent with appropriate public health policy, current scientific information, our available resources, and the scientific and regulatory issues raised by specific GRAS notices. For example, as discussed in Response 92 we intend to continue to include standard language such as that shown in table 1 in responding to GRAS notices. However, this language may evolve over time.

CVM established its Interim Pilot program in June, 2010 (75 FR 31800, Docket No. FDA–2010–N–0215) and filed its first GRAS notice in December 2010. CVM did not have any experience to document as of 2010 and, thus, had not written its own experience document at that time. As of December 31, 2015, CVM had responded to 18 GRAS notices, and has now documented its experience with those 18 GRAS notices with respect to some comments specifically directed to the GRAS notification procedure administered by CVM (Ref. 20; "CVM's experience document"). We discuss CVM's experience with GRAS notices submitted for substances intended for use in animal food in section XXV.

We are ending both the CFSAN Interim Pilot program announced in the proposed rule, and the CVM pilot program announced in Docket No. FDA–2010–N–0215, as of October 17, 2016. On that date, the final rule becomes effective and will govern the GRAS notification procedure.

C. 2010 Report of the Government Accountability Office

As noted in section I.B, from 2008 to 2010 GAO conducted a study related to ingredients used in human food on the basis of the GRAS provision of section 201(s) of the FD&C Act. In 2010, GAO issued a report (Ref. 4) that included a number of recommendations for FDA. We responded to the GAO's recommendations, and that response is also included in the GAO report.

D. 2010 Notice Reopening the Comment Period

As noted in section I.A, we reopened the comment period for the proposed rule to update comments (75 FR 81536). We did so because of the length of time that had elapsed since publication of the proposed rule and because we had identified a number of issues within the scope of the proposed rule that may require further clarification based on CFSAN's experience with GRAS notices during the Interim Pilot program, comments we received on the proposed rule, and GAO's recommendations (75 FR 81536 at 81537). These issues related to the proposed revisions to the criteria for eligibility for classification as GRAS (Issue 1), the proposed establishment of a notification procedure (Issues 2 through 16), and the effect of the proposed notification procedure on existing GRAS affirmation petitions (Issue 17). Accordingly, we requested comments, by March 28, 2011, on the entire proposed rule as well as on the specific issues identified in the 2010 notice.

In Issue 2 in the 2010 notice, we explained our reasons for tentatively concluding that the terms "conclude" and "conclusion" would be more appropriate in lieu of "determine" and "determination" and requested comment on these terms. In the remainder of this document, we generally use the terms "conclude" and "conclusion" in lieu of "determine" and "determination" except when we are describing provisions of the proposed rule (see Response 41).

E. Public Comments

We received submissions, each containing one or more comments, from diverse members of the public, including manufacturers; trade organizations; consulting firms; law firms; public advocacy groups; non-profit organizations; individuals; a Federal Agency; and other organizations. In the remainder of this document, we describe these comments, respond to them, and explain any revisions we made to the proposed rule.

Some comments address issues that are outside the scope of this rule. For example, some comments ask us to add a new definition to part 170, to define the term "harm" that is used in our current definition of "safe" or "safety" (§ 170.3(e)(i)) (where "safe" or "safety" means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use). We did not propose to add a definition of the term "harm" or ask for comment on whether we should do so, and adding a new definition in the final rule for a term that is used in the definition of "safe" and "safety" would broadly affect our regulations for food additives and GRAS substances without opportunity for public comment. As another example, one comment asks us to prepare an alphabetical index of food additive and GRAS regulations and cites the alphabetical list in our Investigations Operations Manual as evidence that it is feasible to develop such a list. Regardless of whether it is feasible to develop such a list, doing so is not within the scope of our proposal to establish a notification procedure for uses of substances that are not listed in our regulations. We do not discuss such comments in this document.

F. Applicability of Discussions in This Document to Both the Human Food Regulations and the Animal Food Regulations

To simplify the discussion in this document, in general we refer to provisions of the proposed rule and the 2010 notice from the perspective of the regulations that would be established in part 170. Unless we say otherwise, however, the issues discussed also apply to the corresponding provisions for part 570. Any reference to CFSAN documents (such as guidance documents) is specific to CFSAN. See section XXV for a discussion of comments and issues specifically directed to substances used in animal food.

G. Use of Pronouns in This Document

In this document, terms such as "we," "our," and "us" refer to FDA. The regulatory text of the final rule for the GRAS notification procedure specifies that the terms "you" and "your" refer to a notifier (*i.e.,* a person who is responsible for a GRAS notice). To simplify the discussion in this document, in general we use pronouns such as "you" and "your" to refer to a notifier, even though some persons who read this document may not be notifiers.

H. Summary of Principal Changes to the Proposed Notification Procedure

In table 2, we briefly describe the principal changes to the GRAS notification procedure in the final rule compared to the proposed rule. In the remainder of this document, we discuss each of these changes in more detail, including our response to comments relevant to these changes. See table 28 for principal changes that are specific to the GRAS notification procedure for substances used in animal food in part 570.

TABLE 2—SUMMARY OF PRINCIPAL CHANGES TO THE PROPOSED NOTIFICATION PROCEDURE

Proposed rule	Final rule
Would not define any terms	Defines the terms "amendment," "GRAS," "GRAS notice," "notified substance," "notifier," "qualified expert," "supplement," "we, our, and us," and "you and your."
Referred to a "GRAS determination"	Refers to a "GRAS conclusion" or "conclusion of GRAS status."
Referred to the statutory GRAS provision as an "exemption"	Refers to the statutory GRAS provision as an "exclusion."
Would not use "Plain Language" techniques as outlined in a Presidential Memorandum dated June 1, 1998 (Ref. 21) and in "Improving Electronic Dockets on Regulations.gov and the Federal Docket Management System: Best Practices for Federal Agencies" (Ref. 22).	Uses "Plain Language" techniques such as pronouns and short regulatory sections.
Was silent on whether you could incorporate into your GRAS notice specifically identified data and information previously submitted to CFSAN or CVM.	Expressly provides for you to incorporate into your GRAS notice specifically identified data and information previously submitted to CFSAN or CVM.
Would not specify individual parts of a GRAS notice	Specifies the seven parts of a GRAS notice.
Would require three paper copies of a GRAS notice	Provides that you may submit a GRAS notice either in electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.
Referred to dated and signed statements in a GRAS notice as a "claim".	Refers to dated and signed statements in a GRAS notice as "signed statements."
Assumed that a notice will not contain any information that is protected from public disclosure under the FOIA.	Specifies that you must not include any information that is trade secret or confidential commercial information in certain sections of the signed statements in your GRAS notice, but does not otherwise prohibit the submission of information that is protected from public disclosure under the FOIA.
Would require that you inform us of the "common or usual name" of the notified substance.	Requires that you provide an "appropriately descriptive term" for the notified substance.
Would not require that you state your view as to whether any data and information in your GRAS notice are exempt from disclosure under the FOIA.	Requires that you state your view as to whether any of the data and information in your GRAS notice are exempt from disclosure under the FOIA (e.g., as trade secret or as commercial or financial information that is privileged or confidential).
Would not expressly require a signed certification regarding the representative and balanced nature of the GRAS notice.	Expressly requires a signed certification that to the best of your knowledge, your GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance.
For a notified substance of natural biological origin, would require source information such as genus and species.	For a notified substance of natural biological origin, requires source information that includes applicable data and information at the subspecies level (e.g., variety, strain) in addition to genus and species.
Would require the method of manufacture (excluding any trade secrets)	Requires a description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured; you may include trade secret information.
Would not expressly require relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce.	When necessary to demonstrate safety, expressly requires relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.
Would require consideration of dietary exposure as part of a comprehensive discussion of the data and information that you rely on to establish safety, using the statutory language of section 409(c)(5)(A) and (B) of the FD&C Act.	Separates the statutory language of section 409(c)(5)(A) and (B) of the FD&C Act into two distinct parts of the GRAS notice: (1) Part 3, which addresses how much of the notified substance consumers would eat as part of the total diet (including exposure from its intended use and all sources in the diet), as well as how much consumers would eat of other substances (e.g., contaminants or byproducts); and (2) Part 6, which requires that you address, in your narrative, the safety of the notified substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet.
Would require a "comprehensive discussion" of, and citations to, generally available and accepted scientific data, information, methods, or principles that you rely on to establish safety.	Requires a narrative (Part 6 of a GRAS notice) and a list of supporting data and information (Part 7 of a GRAS notice).
Would not require consideration of dietary exposure as part of a comprehensive discussion of the data and information that you rely on to establish safety for a conclusion of GRAS status through experience based on common use in food.	Expressly requires consideration of dietary exposure, regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food.
Would require a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination.	Requires that you either: (1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status; or (2) state that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status.
Would not require that you identify data and information that you view as exempt from disclosure under the FOIA.	If you view any of the data and information in your notice as exempt from disclosure under the FOIA, requires that you identify the specific data and information.

TABLE 2—SUMMARY OF PRINCIPAL CHANGES TO THE PROPOSED NOTIFICATION PROCEDURE—Continued

Proposed rule	Final rule
Would not require that you explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety-related data and information.	Requires that you explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety-related data and information.
Would require that the comprehensive discussion include the basis for concluding that there is consensus among qualified experts that there is reasonable certainty that the substance is not harmful under the intended conditions of use.	Uses the term "generally recognized" rather than the term "consensus."
Was silent on whether you could submit an amendment to a GRAS notice.	Expressly provides for you to submit a timely "amendment" to a GRAS notice before we respond to your GRAS notice or cease to evaluate your GRAS notice.
Considered that it was implicit that you could ask us to cease to evaluate a GRAS notice.	Expressly provides that you may ask us to cease to evaluate your GRAS notice, and expressly provides that we will inform you of our decision regarding your request.
We would acknowledge receipt of a GRAS notice within 30 days of receipt.	We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use. If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing. If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provides our reasons for not filing the submission as a GRAS notice.
We would respond to you in writing within 90 days of receipt of the notice.	Within 180 days of filing, we will respond to you by letter based on our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis. If we extend the timeframe, we will inform you of the extension as soon as practicable but no later than within 180 days of filing.
Was silent on procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by USDA's FSIS.	Specifies procedures that apply when the intended conditions of use of a notified substance in human food include use in a product or products subject to regulation by USDA's FSIS.
We noted that, although the decision to submit a GRAS notice would be voluntary, the provisions governing the GRAS notification procedure, including the information to be submitted, would be mandatory.	The regulatory text of the final rule specifies that the data and information in a GRAS notice are considered a mandatory, rather than voluntary, submission for purposes of its status under the FOIA and our public information requirements in part 20.
Was silent on whether you could submit additional information to a GRAS notice after we respond to it.	Expressly provides for you to submit a "supplement" to a GRAS notice after we respond to your GRAS notice or cease to evaluate it.
Would presumptively convert any filed, pending GRAS affirmation petition to a notice on the effective date of the rule. If we did not receive an amendment from the petitioner within 90 days of the effective date of the rule, with information and statements analogous to those in the proposed "GRAS exemption claim," we would consider the converted petition to be inadequate as a notice and would send the petitioner a letter to that effect..	On the effective date of the rule, we will close the docket for any GRAS affirmation petition that is still pending. Any person who submitted a GRAS affirmation petition that is closed may submit a GRAS notice and request that we incorporate the GRAS affirmation petition.

III. Legal Authority

We are amending our regulations in 21 CFR parts 170 and 570 to replace the voluntary GRAS affirmation petition process with a voluntary GRAS notification procedure and to clarify when the intended conditions of use of a substance are eligible for classification as GRAS under our authority in sections 201, 402, 409, and 701 of the FD&C Act (21 U.S.C. 321, 342, 348, and 371). Section 701(a) of the FD&C Act authorizes the Secretary of the Department of Health and Human Services (the Secretary) to issue regulations for the efficient administration of the FD&C Act; under section 1003(d) of the FD&C Act (21 U.S.C. 393(d)), the Secretary is responsible for executing the FD&C Act, including section 701(a), through the Commissioner of Food and Drugs. The FD&C Act requires that all food additives (as defined by section 201(s) of the FD&C Act) be approved by FDA before they are marketed (sections 402(a)(2)(C) and 409 of the FD&C Act). Section 201(s) excludes from the definition of a food additive a substance generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use.

These regulations will help FDA administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically on the question of whether a substance is GRAS under the conditions of its intended use or is a food additive subject to FDA's premarket review. These regulations provide clarification of the GRAS criteria and provide a more efficient procedure.

As an error, the authority citation that we listed for the proposed amendments to part 570 did not include an existing authority citation, *i.e.,* section 408 of the FD&C Act (21 U.S.C. 346a). Nothing in the proposed rule would alter the citation to section 408. Therefore, the authority citation for 21 CFR part 570 continues to include section 408.

As an error, the authority citation that we listed for the proposed amendments to part 170 stated that we were revising the authority citation. Nothing in the proposed rule would alter the authority citation for part 170. Therefore, the authority citation for 21 CFR part 170 states that the authority citation "continues to read" rather than "is revised to read."

(Comment 1) Some comments state that the proposed rule violates the 1958 amendment because FDA would not be fulfilling its statutory duty to oversee food additives, and, therefore, FDA's interpretation of the GRAS provision is arbitrary and capricious. The comments state that the proposed rule violates the 1958 amendment because it would not require companies to notify FDA of a conclusion that the use of a substance is GRAS. One comment states that without mandatory submissions FDA lacks a "comprehensive catalog" of such substances and their dietary exposure, and therefore cannot "police the border between food additives and GRAS substances" and that FDA and food manufacturers do not have access to accurate exposure data and cannot assess the cumulative effect of similar substances. The comment further states that because the proposed rule "establishes no real oversight over the safety of GRAS substances" it violates the 1958 amendment.

(Response 1) We disagree that the voluntary nature of the GRAS notification procedure violates the 1958 amendment. The FD&C Act provides for premarket review by FDA of a food additive, and excludes from this review any substance that is generally recognized, among qualified experts, to be safe under the conditions of its intended use. Although the FD&C Act specifically provides for our review of food additives, it is silent with respect to industry submissions to us on the use of GRAS substances. To administer the provisions of the FD&C Act with respect to the use of GRAS substances, we are retaining the voluntary nature of the GRAS administrative procedure. This rule replaces one longstanding voluntary administrative procedure with a different voluntary administrative procedure.

IV. General Comments on the Proposed Rule

(Comment 2) One comment states that the rule does not give consumers an opportunity to participate in the process before a substance is used in food. Another comment asserts that the lack of an opportunity for public comment or participation is a "major flaw" in the rule.

(Response 2) We disagree that the GRAS notification procedure does not allow for public participation. We proactively disclose to the public information about each GRAS notice that we have filed for evaluation, including the name and address of the notifier; the name of the notified substance; the intended conditions of use of the notified substance; and the statutory basis for the conclusion of GRAS status (*i.e.,* through scientific procedures or through experience based on common use in food). In the past, outside parties who have accessed this information have made us aware of dissenting views about whether available data and information support a conclusion that a notified substance is safe under the conditions of its intended use (see sections III.C.2, III.E, and III.I.1 in CFSAN's 2010 experience document) (Ref. 18). We continue to welcome substantive information from stakeholders regarding the safety of a notified substance. We advise stakeholders who wish to provide us with such substantive information to submit it to the same address where a notifier would send a GRAS notice and ask us to add it to the administrative file for the applicable GRAS notice. This administrative file is maintained by the responsible Center (*i.e.,* CFSAN or CVM). We would consider the submitted information, along with other information that is available to us, on a case-by-case basis.

(Comment 3) One comment asks us to require companies to maintain active and accurate registrations for GRAS substances in a public database.

(Response 3) We decline this request. This comment is suggesting a process not within our regulatory framework and does not provide a legal basis whereby we could require companies to maintain registrations in a public database for substances that are used in food on the basis of the GRAS provision in section 201(s) of the FD&C Act. We note, however, that the final rule provides a framework for making the GRAS notices, and our responses to these notices, available to the public.

(Comment 4) One comment asks us to specify whether the notified substance would be for human or animal consumption. Another comment notes that specifying whether the notified substance is intended for human or animal consumption is important because food for humans is not necessarily appropriate for animals and vice versa.

(Response 4) We agree with these comments. This rule establishes requirements for a GRAS notice about the intended use of a notified substance in human food in part 170 and establishes separate requirements for a GRAS notice about the intended use of a notified substance in animal food in part 570. Regardless of whether the notified substance would be used in human food or in animal food, the notifier must specify the intended conditions of use (see §§ 170.225(c)(4) and 570.225(c)(4)). As discussed in Response 90, we include the intended conditions of use in our publicly available letters responding to GRAS notices.

(Comment 5) One comment notes that the experience highlighted in CFSAN's experience document (Ref. 18) can provide valuable learning that can be of benefit to CVM and asks CFSAN and CVM to strive for harmonization of their requirements and policies in all areas, so the process is not more stringent for one industry than the other.

(Response 5) We agree that CFSAN and CVM can learn from each other's experience with the implementation of the GRAS notification procedure and that procedural and scientific requirements should be consistent as much as is feasible and appropriate. As noted in section II.B, CVM has now documented its experience with 18 GRAS notices with respect to some comments specifically directed to the GRAS notification procedure administered by CVM (Ref. 20).

(Comment 6) One comment urges CFSAN and CVM to put forth similar training and resources for staff assigned to evaluate GRAS notices to decrease the time necessary to complete the evaluation of a GRAS notice.

(Response 6) We staff, equip, and train our employees consistent with our priorities and budgets, which are specific to each Center. As a practical matter, our current organizational framework, in which CFSAN and CVM are both components of the Office of Foods and Veterinary Medicine, promotes interactions between staff in the two Centers.

V. Comments on the Definition of Scientific Procedures

We proposed to amend the definition of "scientific procedures" to specify that scientific procedures include scientific data (such as human, animal, analytical, or other scientific studies), information, methods, and principles, whether published or unpublished, appropriate to establish the safety of a substance. In the 2010 notice, we described comments relevant to this proposed amendment, including comments that support it and a comment that objected to it because, under the proposed amendment, an "unpublished principle" could inappropriately be considered a sufficient scientific procedure for demonstrating the safety of a food substance. We also noted that we had reviewed our use of the term "study" in the proposed companion change to the definition of scientific procedures and explained our view that, to be a "procedure," data, information, methods, or principles would need to be acquired or applied. We stated that we were considering whether to revise the definition of scientific procedures in § 170.3(h) to include the application of scientific data (including, as appropriate, data from human, animal, analytical, and other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance (see Issue 1, 75 FR 81536 at 81537–81538). We requested comment on this issue.

Several comments support the proposed amendment to the definition of scientific procedures as described in the proposed rule, with the potential modifications described in the 2010 notice, because the revised definition would more accurately reflect the state of contemporary science than the definition it would replace. Some comments express the view that specifying that it is "the application" of unpublished scientific data, information, or methods that would corroborate GRAS status would make it clear that a submission to us regarding a conclusion of GRAS status may include discussions of unpublished studies. In the following paragraphs, we discuss comments that suggest additional changes to the definition of "scientific procedures." After considering these comments, we are finalizing the definition of scientific procedures as proposed, with the modifications described in the 2010 notice and with editorial changes as shown in table 29.

(Comment 7) One comment that supports the potential modifications to the definition of "scientific procedures" as described in the 2010 notice asks us to incorporate an additional clarification that "scientific principles appropriate to establishing the safety of a substance" encompass consideration of both the data supporting the safety of the substance and the probable dietary exposure.

(Response 7) To the extent that the comment means that "scientific procedures" (rather than "scientific principles") encompass consideration of both the data supporting the safety of the substance and the probable dietary exposure, we agree. However, it is not necessary to revise the definition of scientific procedures to make that clear. The definition of "scientific procedures" already specifies the application of data from human, animal, analytical, or other scientific studies, and the definition of "safe" or "safety" in § 170.3(i) includes probable dietary exposure as a factor that must be considered in determining safety.

As discussed in the 2010 notice, "principle" can be defined as a fundamental cause or basis of something; a primary element, force, or law determining a particular result; or a fundamental truth or proposition on which others depend. Thus, a principle is a different genre than data, information, and methods. Therefore, although we agree that "scientific procedures" encompass consideration of both the data supporting the safety of the substance and the probable dietary exposure, we disagree that the data supporting the safety of the substance and the probable dietary exposure are "scientific principles."

VI. Comments on the Criteria for Eligibility for Classification as GRAS

Section 170.30 specifies three types of criteria for eligibility for classification as GRAS: (1) General criteria; (2) criteria for classification as GRAS through scientific procedures; and (3) criteria for classification as GRAS through experience based on common use in food. We proposed to amend all three criteria to: (1) Clarify that the safety standard for a GRAS substance is identical to the safety standard for a food additive; (2) clarify the types of technical evidence of safety that could form the basis for classification as GRAS through scientific procedures, and clarify the role of publication in establishing general recognition of safety through scientific procedures; and (3) make conforming changes to the criteria for eligibility for classification as GRAS through experience based on common use in food. We proposed these amendments in association with our concurrent proposal to replace the GRAS affirmation petition process with a GRAS notification procedure. In the 2010 notice, we stated that we were considering an additional revision to correspond with the revision to the definition of scientific procedures (see section V in this document and Issue 1, 75 FR 81536 at 81537–81538 in the 2010 notice).

In the following sections, we discuss comments that disagree with one or more aspects of our proposal to amend the criteria for eligibility for classification as GRAS, with the potential modifications described in the 2010 notice (see, *e.g.,* Comment 9 and Comment 13); ask us to clarify how we will interpret the revised criteria or offer suggestions for how we should interpret the revised criteria (see, *e.g.,* Comment 12, Comment 16, Comment 17, and Comment 18); or suggest one or more changes to the revised criteria (see, *e.g.,* Comment 10, Comment 19, and Comment 20). After considering these comments, we are establishing the criteria for eligibility for classification as GRAS for use of a substance in human food as proposed, with the modification we described in the 2010 notice and with editorial, clarifying, and conforming changes as shown in table 29. See section XXV.B for a description of additional changes we made to the criteria for eligibility for classification as GRAS for use of a substance in animal food.

A. General Criteria for Eligibility for Classification as GRAS

We proposed to revise the final sentence of § 170.30(a) to specify that general recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use. As discussed in the proposed rule, we proposed this revision to clarify that the safety standard for a GRAS substance is identical to the safety standard for food additives (see § 170.3(i)) and that a GRAS substance is neither more safe, nor less safe, than an approved food additive (62 FR 18938 at 18942). We received no comments that disagreed with this proposed revision and are finalizing § 170.30(a) as proposed with conforming changes as shown in table 29.

See section XXV.B regarding revisions to the general criteria for eligibility for classification as GRAS for a substance used in animal food.

B. Criteria for Eligibility for Classification as GRAS Through Scientific Procedures

We proposed to amend the criteria for eligibility for classification as GRAS through scientific procedures to: (1) Require that the data and information for general recognition of safety be "generally available and accepted," and (2) broaden the types of acceptable data and information by replacing "studies" with "data, information, methods, or principles." In the 2010 notice, we stated that we were considering whether to revise these criteria with respect to the types of acceptable data and information to include "the application" of generally available and accepted scientific data, information, or methods, as well as "the application" of scientific principles" (see section V in this document and Issue 1, 75 FR 81536 at 81537–81538 in the 2010 notice).

See section XXV.B regarding revisions to the criteria for eligibility for classification as GRAS through scientific procedures for a substance used in animal food.

(Comment 8) One comment asserts that the criterion for the generally available data or information establishing safety to ordinarily be published is artificial. Other comments point out that information that is not published can nonetheless be considered "generally available." Some comments object to the proposed amendment to the criteria for eligibility for classification as GRAS through scientific procedures and assert that it would de-emphasize or eliminate the existing criterion for peer-reviewed studies.

(Response 8) Regardless of whether the data and information are published or unpublished, under the revised criteria a GRAS conclusion must be based on data and information that are generally available and accepted, and as such, are publicly available. As we stated in the proposed rule, the common knowledge element of the GRAS standard precludes a GRAS conclusion if the data and information (*e.g.*, as evaluated by a "GRAS panel") are only available in files that are not publicly accessible, such as in confidential industry files (62 FR 18938 at 18943). We disagree that the criterion for the generally available data or information establishing safety to ordinarily be published is artificial. Publication in a peer-reviewed scientific journal is the usual mechanism to establish that scientific information is generally available, provided that the journal is representative of scientific publications accessed by the expert scientific community (62 FR 18938 at 18943). Nonetheless, the revised criteria provide flexibility for supporting a conclusion of GRAS status through the application of scientific data, information, or methods that are generally available through a mechanism other than publication in a peer-reviewed scientific journal, such as publication in a textbook and other sources of technical literature. One example of another source of technical literature is the Joint Expert Committee on Food Additives (JECFA, a joint committee of the Food and Agriculture Organization/World Health Organization). We note, however, that the mere fact that data and information are published or otherwise publicly available does not satisfy the criteria for general recognition of safety. Regardless of the mechanism of making data and information generally available to qualified experts, it must be plausible that qualified experts would be accessing those data and information using that mechanism. For example, scientists who routinely access peer-reviewed journals in electronic form on the Internet may avoid Internet "publications" about a scientific topic when the "publication" is not associated with a reputable scientific institution.

We have not changed our position on the importance of peer review. The basis for GRAS status continues to be the application of generally available scientific data, information, and methods, which ordinarily are published (and, thus, are subject to peer review as part of the scientific publication process for most journals). We continue to believe that whether scientific data, information, and methods have been peer reviewed before publication in a scientific journal that is representative of scientific publications accessed by the expert scientific community is a factor that bears on the objectivity and scientific merit of study, and is a variable we consider in determining whether experts accept the report of a scientific investigation as a credible report and whether there is general knowledge of the scientific investigation.

CFSAN's 2010 experience document (Ref. 18) provides factual information on how CFSAN already has interpreted the criteria for eligibility for classification of GRAS status through scientific procedures for GRAS notices CFSAN received during the Interim Pilot program (see section III.A.1 of CFSAN's 2010 experience document), and we intend to continue this approach in the future. In most cases, a submitted GRAS notice described a mixture of information published in peer-reviewed journals, information (such as in textbooks) that was generally available in a form other than a peer-reviewed journal, and unpublished information. As shown in table 1 in CFSAN's 2016 experience document, CFSAN had no questions about GRAS status based on this mixture of information in approximately 81 percent of the GRAS notices CFSAN evaluated between 1998 and 2015 (Ref. 19). Importantly, CFSAN's evaluation of the basis for a conclusion that a use of a food substance is GRAS in addition to being safe was a case-by-case evaluation. As discussed in section III.A.4 of CFSAN's 2010 experience document, in some cases it was CFSAN's view that the available data and information were sufficient to demonstrate safety, but not GRAS status, and CFSAN established a food additive regulation for the use of the substance in response to a food additive petition for that use (Ref. 18).

(Comment 9) Some comments state that all available relevant data, including unpublished data, should be used in evaluating GRAS status. Some of these comments cited the placement of the word "ordinarily" in the criteria for classification as GRAS through scientific procedures as support for this interpretation. Several comments urge us to interpret, in a flexible manner, the proposed criteria for the scientific data, information, methods or principles that establish safety to be "generally available and accepted" and "ordinarily . . . published."

(Response 9) We agree that all relevant data should be used in evaluating GRAS status, including unpublished data. However, regardless of whether data and information are published or unpublished, a GRAS conclusion based on scientific procedures must be based on data and information that are generally available and accepted, and as such, are publicly available (see Response 8). The GRAS criteria for scientific procedures, as established in 1976, state that the applicable data and information are "ordinarily" published and may be "corroborated" by unpublished data and information, and this rule retains these criteria. The common meaning of "corroborate" is to make more certain or confirm (Ref. 23). Although unpublished data and information can confirm a conclusion of GRAS status, to satisfy GRAS criteria qualified experts must be able to conclude that the substance is not harmful under the conditions of its intended use without access to "corroborative" information (see § 170.30(a)). Under this rule, a notifier is required to explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to non-public safety-related data and information considered in reaching a conclusion of GRAS status (see § 170.250(e)).

Whether data and information are corroborative of safety, rather than establish safety, depends on what those data and information are and how they relate to the safety assessment, not just whether they are published or otherwise publicly available. Whereas unpublished data and information that have a bearing on a safety conclusion, and therefore could help confirm a safety conclusion based on other data and information, in general, can only be considered as corroborative in the context of a GRAS conclusion, published data and information may be either the basis for a safety conclusion or corroborative of a safety conclusion, depending on the nature of the data and information. For example, a published 90-day toxicology study could be the basis for a safety conclusion, but a preliminary toxicology study conducted primarily for the purpose of selecting the doses to be used in that 90-day toxicology study is unlikely to be the basis for a safety conclusion, regardless of whether that preliminary toxicology study is published.

See also the discussion in Response 58 regarding the requirement for you to submit a signed statement certifying that, to the best of your knowledge, your GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance (§ 170.225(c)(9)). See also the discussion in section XVII regarding the requirement for your narrative to identify, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available (§ 170.250(c)).

(Comment 10) One comment asks us to explicitly acknowledge publication of information in the secondary scientific literature as a mechanism to satisfy the standard for general availability.

(Response 10) We decline this request. In general, the secondary scientific literature includes publications (such as review articles, textbooks, and compendia) which disseminate the views of scientists who are critically evaluating a primary body of data and information already published in peer-reviewed scientific journals that are representative of scientific publications accessed by the expert scientific community (*i.e.,* the primary scientific literature). Whether a publication in the secondary scientific literature satisfies the criteria for GRAS status through scientific procedures is a case-by-case determination that depends on the circumstances. See section III.A.1 of CFSAN's 2010 experience document (Ref. 18) for examples of how CFSAN considered publications in the secondary scientific literature during the Interim Pilot program. When the underlying data being reviewed in the secondary scientific literature are themselves generally available, a publication in the secondary scientific literature can provide evidence that the data and information discussed in the publication are generally accepted as well as generally available. If a publication in the secondary scientific literature discusses data and information that are available to the authors, but not previously published in the primary scientific literature, whether that publication could satisfy the "generally available" aspect of the criteria for eligibility for GRAS status through scientific procedures would depend on the nature and extent of the discussion in the publication. For example, a very general statement that a study was conducted and reported no adverse findings would not suffice to make the study "generally available"; instead, such a statement would merely be a generally available opinion about data and information, in that study, that are not generally available. Such a publication may satisfy the "generally accepted" aspect of the criteria for GRAS status through scientific procedures for that study, but would be insufficient, by itself, to satisfy the "generally available" aspect of those criteria. However, a comprehensive description in the secondary scientific literature of a previously unpublished study, including details similar to details that would be included in a publication in the primary scientific literature, may suffice to make the study published in the secondary scientific literature "generally available." In such circumstances, the publication in the secondary scientific literature may be able to satisfy both the "generally available" and "generally accepted" aspects of the criteria for eligibility for GRAS status through scientific procedures for certain data and information.

(Comment 11) One comment asks us to recognize that publication of an opinion of a specially convened "expert panel" would satisfy the standard for general availability because, in the comment's view, review by such a panel would be equivalent to, or exceed, peer review. (By "expert panel," we assume that the comment is referring to a "GRAS panel", *i.e.,* a panel of individuals convened for the purpose of evaluating whether the available scientific data, information, and methods establish that a substance is safe under the conditions of its intended use in food. See the discussion in section III.A.1 of CFSAN's 2010 experience document (Ref. 18).)

(Response 11) We would consider publication of an opinion of a specially convened "GRAS panel" to be part of the secondary scientific literature as discussed in Response 10. As with any publication in the secondary scientific literature, when the underlying data being reviewed in a published "GRAS panel" opinion are themselves generally available, a published "GRAS panel" opinion could provide evidence that the data and information discussed in the publication are generally accepted, depending on factors such as the subject matter expertise of the members of the GRAS panel and whether the members of the GRAS panel would be considered representative of experts qualified by scientific training and experience to evaluate the safety of the substance under the conditions of its intended use. For example, a "GRAS panel" opinion published by scientists without expertise appropriate to address the applicable safety questions could not provide evidence that the conclusions in the publication are "generally accepted."

If a published "GRAS panel" opinion discusses data and information that are available to the members of the GRAS panel, but not generally available to qualified experts, whether that publication could satisfy the "generally available" aspect of the criteria for eligibility for GRAS status through scientific procedures would depend on the nature and extent of the discussion in the publication (see Response 10). Unless both criteria, *i.e.,* "generally available" and "generally accepted", are satisfied, there would be no basis for a conclusion of GRAS status based on a published "GRAS panel" opinion.

(Comment 12) One comment states that all available relevant data, including unpublished data, should be used in evaluating GRAS status, as long as any unpublished data are generated by appropriate and valid scientific methods as judged and reviewed by an external qualified GRAS panel and are accessible to FDA for review.

(Response 12) We agree that all available relevant data should be used in evaluating whether a use of a substance in food is GRAS through scientific procedures. By "all relevant data," we mean data that support a conclusion of GRAS status as well as data that are inconsistent with a conclusion of GRAS status, not just whether the data are published. (See §§ 170.225(c)(9) and 170.250(c) and the discussion in Response 58, Response 69, and Response 78.) We also agree that it is appropriate for unpublished data to be generated by valid scientific methods and to be accessible to FDA for review (*e.g.,* when such data are cited in a submission to FDA). In addition, we have acknowledged the practice of convening an external "GRAS panel" to evaluate whether the available scientific data, information, and methods demonstrate that a substance is safe under the conditions of its intended use in food (see section III.A.1 of CFSAN's 2010 experience document) (Ref. 18). However, we disagree that information that is not generally available to qualified experts could be used as evidence for a GRAS conclusion merely because a GRAS panel has reviewed it. Such information would need to be considered, but generally would only be corroborative of safety. (See Response 9 and Response 11.)

(Comment 13) One comment asserts that the proposed rule treats the findings of GRAS panels as equivalent to determinations by authoritative bodies and peer reviewed published articles.

(Response 13) We disagree. In the proposed rule, we noted that the basis for concluding there is expert consensus about the safety of a substance under the conditions of its intended use may be quite varied, and described common mechanisms that have been used to do so. We stated that these common mechanisms included publication in the primary, peer-reviewed scientific literature; publication in the secondary scientific literature; documentation of the opinion of an "expert panel" that is specifically convened for this purpose; and the opinion or recommendation of an authoritative body such as the National Academy of Sciences or the Committee on Nutrition of the American Academy of Pediatrics on a broad or specific issue that is related to a conclusion of GRAS status (62 FR 18938 at 18940–18941). We also stated that there could be a basis to conclude that there is expert consensus that the published results of a particular safety study (*i.e.,* the primary scientific literature) establish the safety of a substance for its intended use if the study raises no safety questions that experts would need to interpret and resolve (62 FR 18938 at 18943). In addition, technical literature from JECFA can provide evidence that generally available safety data and information are generally accepted (see section III.A.1 of CFSAN's 2010 experience document (Ref. 18)).

However, acknowledging that the opinion of an "expert panel" (which we now refer to as a "GRAS panel") has been used to provide evidence that safety data and information are generally accepted does not mean that these mechanisms are "equivalent." Whether the findings of a GRAS panel, a determination by an authoritative body, or a peer-reviewed scientific study provide sufficient evidence that safety data and information are generally accepted would depend on the specific findings of the GRAS panel, the specific determination by the authoritative body, and the data and information in the peer-reviewed scientific study rather than on the classification of the mechanism for providing evidence that safety data and information are generally accepted.

(Comment 14) One comment asks us to develop and publish guidelines regarding specific duties that would be expected of any GRAS panel. This comment suggests that such guidelines could include recommendations for: (1) Number of panel members; (2) measures of "general acceptance," such as a majority (rather than unanimous) opinion and the impact of a dissenting opinion; and (3) the content of a letter from a GRAS panel.

(Response 14) See Response 125. We intend to issue for public comment a draft guidance to address GRAS panels.

(Comment 15) Some comments assert it can be difficult to publish data and information that do not raise an issue of concern.

(Response 15) We infer this comment to refer primarily to toxicology studies. Toxicology studies are designed to provide information about potential adverse effects from exposure to a substance and any dose-response relationship. Although studies that fail to identity any adverse effects may be difficult to publish, some scientific journals report the findings of such studies. (See section III.A.1 of CFSAN's 2010 experience document (Ref. 18)).

(Comment 16) One comment asks us to require that both toxicology and exposure data be published because a safety assessment for the use of a substance in food requires consideration of both.

(Response 16) We agree that a safety assessment for the use of a substance in food requires consideration of both safety information (such as toxicology studies) and dietary exposure (*i.e.,* the amount of the substance that consumers are likely to eat or drink). Toxicology data are ordinarily published.

A premarket exposure assessment typically would be calculated by applying generally available and accepted methods to two types of data and information: (1) Generally available and accepted data about food consumption; and (2) specific food categories, and levels of use in those food categories, projected by the sponsor of a food additive petition or by the proponent of GRAS status (Ref. 24 and Ref. 25). Using generally available and accepted data about food consumption, a qualified expert who has access to the specific food categories and associated levels of use intended by the proponent of GRAS status can calculate an estimated dietary exposure. When the proponent of GRAS status submits a GRAS notice, the proponent must: (1) Provide data and information about dietary exposure (see § 170.235); and (2) include a narrative that addresses the safety of the notified substance, considering all dietary sources (see § 170.250). Those calculations and discussions included in the GRAS notice are subject to the public disclosure provisions of this rule (see § 170.275) and, thus, would be available to the expert scientific community. However, when the proponent of GRAS status does not submit a GRAS notice, the expert scientific community that does not have access to the specific food categories and associated levels of use would not be able to calculate an estimated dietary exposure. When the available data and information suggest that the specific food categories and associated levels of use must be carefully chosen to keep consumption of the substance in a safe range (*e.g.,* when fortifying food with certain vitamins), the expert scientific community that does not have access to the specific food categories and associated levels of use would not be able to reach a conclusion about whether the substance is safe under the conditions of its intended use, and GRAS criteria would not be satisfied.

After market entry of the substance, it may be appropriate to re-assess dietary exposure. For example, dietary exposure may need to be reassessed when a key assumption in the methodology is changed; as dietary consumption patterns change; when there is an unresolved question about consumer intake; when there is a small margin of exposure; or when other new information becomes available. As with a premarket exposure assessment, a postmarket exposure assessment typically would be calculated by applying generally available and accepted methods to two types of data and information: (1) Generally available and accepted data about food consumption; and (2) specific food categories, and levels of use in those food categories. In some cases, postmarket exposure assessments have been published so that the expert scientific community has access to them. For example, exposure assessments have been published for some sweeteners using relative sweetness as the basis of the estimate (Ref. 26). As another example, estimates of dietary exposure to caffeine have been published to address consumer intake and patterns of use (Ref. 27 through Ref. 29). However, as with a premarket exposure assessment, when a postmarket exposure assessment is not publicly available, the expert scientific community that does not have access to the specific food categories and associated levels of use would not be able to reach a conclusion about whether the substance is safe under the conditions of its intended use when the available data and information suggest that the specific food categories and associated levels of use must be carefully chosen to keep consumption of the substance in a safe range.

(Comment 17) One comment asks us to recognize that published literature does not need to address a specific substance, but could involve publications on a class of substances or a related substance to support a conclusion that the use of a substance is GRAS through scientific procedures.

(Response 17) We agree that published information for a specific substance is not always necessary to support a conclusion that the use of a substance is GRAS through scientific procedures. For example, there may be situations where the safety of the use of the substance in food can be demonstrated by relevant published information on a closely, structurally related compound. In such cases, the analysis leading to the conclusion of GRAS status should explain how the information on the closely, structurally related compound is relevant to the safety assessment of the substance being evaluated. In other cases, there may a body of information published in the primary or secondary literature about a class of substances, which reflect generally available and accepted data and information that can be called to bear on the safety assessment of a specific substance. For example, generally available metabolism information about commonly consumed components of food, such as carbohydrates, lipids, and proteins, could support a conclusion that a specific substance is GRAS under the conditions of its intended use.

To help ensure that the data are, in fact, relevant to the safety assessment of the substance being evaluated, we strongly encourage any person who intends to rely on data and information regarding a class of substances, or a specific substance related to the substance that would be added to food, to submit any conclusion of GRAS status to FDA via the GRAS notification procedure.

(Comment 18) One comment states that the use of an approved food additive can, through the passage of time, become GRAS as the substance becomes widely used and as information about the substance becomes publicly available.

(Response 18) We disagree that widespread use of an approved food additive as time passes has any bearing on the eligibility of this use for classification as GRAS. Eligibility for classification as GRAS through scientific procedures would depend on the status of the information—as generally available and generally accepted—rather than on the amount of time that a food additive has been used in food. However, in general, much of the data submitted for our review of a food additive contains unpublished data and trade secret or confidential information that is neither published nor otherwise generally available. Although the safety data are available for public disclosure under 21 CFR 171.1(h)(1), they typically are based on unpublished studies sponsored by the petitioner.

See also the discussion in Response 19 regarding the impact of the passage of time and the discussion in Response 79 that the qualified experts who evaluate the basis for a conclusion that the notified substance is safe under the conditions of its intended use must not exclusively be "FDA's experts."

(Comment 19) One comment asks us to exclude uses of "novel" substances from consideration for eligibility for classification as GRAS. The comment asserts that novel or newly discovered uses of substances that are the subject of a conclusion of GRAS status are in conflict with the original intent of the 1958 amendment and the plain meaning of "generally recognized," because there is no history of safe use for these substances. The comment also states that similar "general recognition" provisions for new drugs are not interpreted to allow industry-made safety determinations for new or novel drugs.

(Response 19) We do not have a regulatory definition for a "novel" substance. As a general matter, section 201(s) of the FD&C Act provides two alternatives for general recognition of safety—through scientific procedures, or through experience based on common use in food. Section 201(s) does not limit eligibility, or otherwise exclude, the use of a substance from classification as GRAS through scientific procedures if there is no history of use. Likewise, section 201(s) does not limit eligibility, or otherwise exclude, the use of a substance from classification as GRAS through scientific procedures based on other criteria, such as whether a substance or its use in food is "novel" or "newly discovered." Unlike the definition of a "new drug" in section 201(p) of the FD&C Act, section 201(s) does not require that a food ingredient be used "to a material extent or for a material time under such conditions" before it can become GRAS. Rather, the criteria for eligibility for classification as GRAS depend on whether generally available and accepted data and information establish that the substance is safe under the conditions of its intended use.

However, a conclusion of GRAS status must be based on common knowledge throughout the scientific community knowledgeable about the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (§ 170.30(a)), and a substance cannot be considered GRAS when its characteristics are known to only a few experts (Final rule establishing GRAS criteria, 41 FR 53600, December 7, 1976). In addition, the passage of time is relevant in an evaluation of whether a substance is GRAS under the conditions of its intended use. In our 1974 proposed rule on general recognition of safety and prior sanctions for food ingredients, we acknowledged that there would be at least some gap between the gathering of the scientific knowledge necessary to provide the toxicological underpinning for general recognition of safety and the dissemination to and assimilation by the scientific community of this material that is necessary for general recognition of safety to exist." (39 FR 34194 at 34194, September 23, 1974). More recently, the discussions in sections III.A.4 and IV.K of CFSAN's 2010 experience document (Ref. 18) show our approach to the time gap between the publication of safety data and the use of the published safety data to support a conclusion of GRAS status during the Interim Pilot program. See also Response 67 regarding nanotechnology applications in food substances.

(Comment 20) One comment asserts that we must define the extent of agreement needed to establish a consensus among qualified experts, and that we must exclude from eligibility for classification as GRAS any substance whose safety has been called into question by expert authorities or authoritative entities within the scientific community.

(Response 20) The proponent of a GRAS conclusion for a food substance must demonstrate that the conditions of use of the substance satisfy the definition of "safe" in our regulations (*i.e.,* that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (see § 170.3(i)). The proponent of GRAS status also must demonstrate that there is common knowledge about this safety throughout the knowledgeable scientific community (§ 170.30(a)). Although courts have established that general recognition of safety requires a consensus of expert opinion regarding the safety of the use of the substance, (see, *e.g., United States* v. *Western*

Serum Co., Inc., 666 F.2d 335, 338 (9th Cir. 1982) (citing *Weinberger* v. *Hynson, Westcott & Dunning,* 412 U.S. 609, 629–32 (1973)), we disagree that we must define the extent of agreement needed to establish such a consensus. Courts have established that general recognition of safety does not require unanimous agreement. See, *e.g., United States* v. *Articles of Drug * * * 5,906 Boxes,* 745 F.2d 105, 119 n. 22 (1st Cir. 1984); *United States* v. *Articles of Food and Drug (Coli-Trol 80),* 518 F.2d 743, 746 (5th Cir. 1975) ("What is required is not unanimous recognition but general recognition"). Importantly, general recognition of safety does not exist if there is a genuine dispute among qualified experts that the use of a substance is safe. See, *e.g., Premo Pharmaceutical Laboratories* v. *United States,* 629 F.2d 795, 803–4 (2nd Cir. 1980) ("genuine dispute among qualified experts" precludes finding of general recognition, and no general recognition existed as a matter of law where there was a "sharp difference" of expert opinion); *United States* v. *Article of Food * * * Coco Rico,* 752 F.2d 11, 15 n 6 (1st Cir. 1985) (substance was not GRAS as a matter of law based on existence of "genuine dispute among qualified experts" regarding safety of use). For discussions of additional judicial decisions bearing on the criteria for eligibility for classification as GRAS, see the notice of declaratory order providing our final determination regarding partially hydrogenated oils (80 FR 34650).

A conclusion of GRAS status must be based on the totality of the publicly available and corroborative evidence about the safety of the substance under the conditions of its intended use, including both favorable and potentially unfavorable information. Thus, reports of expert authorities or authoritative entities within the scientific community may indicate that there is no general recognition of safety when the reports call into question the safety of a substance for use in food. However, we disagree that the outcome of an evaluation of such information can be predetermined as suggested by the comments. Regardless of whether particular scientific data and information lead experts to conclude that a substance is safe under the conditions of its intended use, or raise questions about the safety of the substance under the conditions of its intended use, the evaluation of whether a use of a substance in food is safe, and whether safety is generally recognized, is a case-by-case evaluation. For example, data and information that lead expert authorities or authoritative entities within the scientific community to raise a concern about the safety of the substance under the conditions of its intended use in food would have reduced significance if the concern was related to a contaminant in the substance and scientifically valid data and information supplied by the proponent of GRAS status provide evidence that an improved method of manufacture eliminates that contaminant.

See also Response 77, in which we explain that we proposed to provide the judicial interpretation of section 201(s) of the FD&C Act in the requirement for the comprehensive discussion of the notifier's basis for a conclusion of GRAS status to provide more context to notifiers than merely repeating the statutory language. However, as discussed in Response 77, we have decided to use the statutory language (*i.e.,* "generally recognized") rather than the proposed term "consensus" in the submission requirements for a GRAS notice to mirror the GRAS criteria in § 170.30, which continue to use the statutory language rather than the consensus standard applied by the courts in applying the statutory language to specific situations.

(Comment 21) In the proposed rule, we asked for comment on the potential for a conclusion of GRAS status through scientific procedures to be based in part on the "substantial equivalence" of the applicable substance to a substance that is GRAS through experience based on common use in food. One comment agrees with the view, expressed in a 1996 JECFA Report (Ref. 30) and reported in the proposed rule (62 FR 18938 at 18944), that "substantial equivalence" embodies the concept that if a new food component is found to be substantially equivalent to an existing food component, the food component could be considered to be as safe as the existing food component, after taking into account any processing that the food component may undergo as well as the intended use and the intake by the population. Several comments assert that the concept of substantial equivalence, although useful, is nonetheless ambiguous. One comment asks us to clearly state our interpretation of this concept in the final rule.

(Response 21) We have decided not to include the term "substantial equivalence" in the regulatory text of this rule, because whether, and to what extent, similarity between two substances could support a conclusion of GRAS status depends on too many situation-specific variables. As discussed in section IV.N of CFSAN's 2010 experience document, GRAS notices filed during the Interim Pilot program that relied on the concept of "substantial equivalence" generally addressed alternative sources of enzymes already used in food (Ref. 18). Most of these notices both emphasized the similarities of the new enzyme preparations to existing enzyme preparations and explained the differences between the new enzyme preparation and currently used enzyme preparations. However, none of these GRAS notices relied solely on the concept of "substantial equivalence." Instead, these notices also described other applicable data and information, such as data and information about the biological source of the enzyme preparation; the method of manufacture of the enzyme preparation; constituents of the enzyme preparation that derive from the source organism or the manufacturing process; the technical effect of the enzyme preparation; dietary exposure to the enzyme preparation; specifications for the enzyme preparation; and applicable safety studies.

C. Criteria for Eligibility for Classification as GRAS Through Experience Based on Common Use in Food

We proposed to amend the criteria for eligibility for classification as GRAS through experience based on common use in food (§ 170.30(c)(2)) to state that persons who claim that use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that claim in accordance with the GRAS notification procedure. We received no comments that disagreed with this proposed amendment and are finalizing it as proposed, with conforming changes as shown in table 29.

See section XXV.B regarding revisions to the criteria for eligibility for classification as GRAS through experience based on common use in food for a substance used in animal food.

D. Other Comments on the Criteria for Eligibility for Classification as GRAS

(Comment 22) One comment asserts that the proposed rule would add unnecessary complexity to continued use of substances currently presumed to be GRAS. This comment also asserts that the proposed rule would remove the "pre-1958 exemption" and, as a result, would place an unnecessary burden on food producers and processors with respect to substances that are the subject of previous conclusions of GRAS status.

(Response 22) These comments are unclear. By "pre-1958 exemption" these comments could mean a conclusion of GRAS status through experience based on common use in food, which requires common use in food before January 1, 1958. Alternatively, these comments could be referring to the statutory exception from the definition of "food additive" for a substance that is the subject of a prior sanction within the meaning of section 201(s)(4) of the FD&C Act and part 181 (21 CFR part 181). Either way, nothing in this rule would affect a lawful use of a food substance that is GRAS based on common use in food prior to January 1, 1958 or that is the subject of a prior sanction. This rule does not remove GRAS status based on common use in food prior to January 1, 1958. Likewise, the lawful use of a substance listed in part 181 as being the subject of a prior sanction is not affected by this rule.

However, any person who relies on a conclusion of GRAS status through experience based on common use in food prior to 1958 or on a prior sanction within the meaning of section 201(s)(4) of the FD&C Act needs to consider whether the conditions of use associated with the applicable substance, such as the foods in which the substance would be used and the levels of use of the substance, are within the scope of these statutory provisions. As discussed in section I.D, in 2010 we issued warning letters informing four companies marketing caffeinated alcoholic beverages that caffeine, as used in the companies' products, is an unsafe food additive, and therefore the products are adulterated under section 402(a)(2)(C) of the FD&C Act, and the companies subsequently ceased distribution of these products. Thus, we advise any manufacturer or distributor to carefully consider whether there is adequate support for concluding that a substance is GRAS under the conditions of its intended use and to submit a GRAS notice to us if it intends to manufacture or distribute a food product containing a substance that has been used in food as a GRAS substance under conditions of use different from those in the manufacturer's or distributor's product.

In addition, new data and information may call into question the safety of a substance used in food as a GRAS substance, whether the basis for a conclusion of GRAS status is through experience based on common use in food or through scientific procedures. As discussed in section I.A, in 1969 we deleted various cyclamate salts from the GRAS list because they were implicated in the formation of bladder tumors in rats; as discussed in section I.D, we recently issued a declaratory order making a final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food (80 FR 34650).

(Comment 23) One comment asks us to require minimum safety or short-term toxicology studies for all conclusions of GRAS status, regardless of whether the conclusion is through scientific procedures or through experience based on common use in food before 1958. This comment explains that such studies could corroborate safety when GRAS status is based on common use on food, *e.g.,* by taking into account any impact of the manufacturing process on food safety.

(Response 23) We decline this request. We agree that the method of manufacture can impact safety, regardless of whether GRAS status is through experience based on common use on food or through scientific procedures. See, *e.g.,* our guidance entitled "Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives" (Ref. 6). The rule requires submission of a description of the method of manufacture in sufficient detail to evaluate the safety of the notified substance as manufactured, regardless of whether the basis for the conclusion of GRAS status is through scientific procedures or through experience based on common use in food (see § 170.230(b)). If the method of manufacture has changed over time, a new evaluation of GRAS status based on scientific procedures may be warranted. We advise any manufacturer of a substance that is used in food based on a conclusion of GRAS status to carefully consider the impact of its method of manufacture on the safety of the substance before introducing the substance into commerce.

We disagree that the rule must require minimum safety or short-term toxicology studies for all conclusions of GRAS status because the kinds of data and information needed to demonstrate safety (or that could be used to corroborate safety) will vary based on the substance and its intended use. A conclusion of GRAS status based on scientific procedures must be based on the same quantity and quality of scientific evidence as is required to obtain approval of a food additive (§ 170.30(b)). We have issued guidance on the types of data and information in support of a food additive petition, and these types of data and information would be useful in the evaluation of the safety of a substance when the proponent of the substance seeks to demonstrate that the substance is GRAS under the conditions of its intended use (see Response 37 and Response 66).

For a safety assessment of a chemical, the specific types of data and information generally follow from the chemical structure and estimated dietary exposure of the substance. For example, chemistry data, including manufacturing information, as well as information sufficient to estimate exposure, are necessary to consider in arriving at a conclusion of GRAS status. Whether toxicological studies are necessary to demonstrate safety depends on the properties of the substance such as the presence or absence of chemical alerts, physical properties, and physiological fate of the substance. For example, well understood and accepted metabolism information about a substance that is a component of commonly consumed foods (such as vegetables or fruits) may provide sufficient safety information to arrive at a conclusion of GRAS status at a specified level of the use of that substance in food. As discussed in section III.A.2 of CFSAN's 2010 experience document, during the Interim Pilot program it was CFSAN's view that toxicological studies were not necessary to evaluate the safety of substances such as carrot fiber and dried orange pulp (Ref. 18). Likewise, for simple substances (such as minerals and their salts) that are readily dissociated to components that have long been viewed as GRAS (*e.g.,* by a listing in part 182 or by a GRAS affirmation regulation in part 184), toxicological studies would likely not be necessary. As discussed in section III.A.2 of CFSAN's 2010 experience document, during the Interim Pilot program it was CFSAN's view that toxicological studies were not necessary to evaluate the safety of substances such as potassium bisulfate and seaweed-derived calcium (with calcium carbonate as the major component) (Ref. 18).

For a safety assessment of a substance produced from a microorganism, the specific types of data and information generally follow from the identity of the microorganism and how the substance is produced from that microorganism in addition to the substance itself. For example, the safety of a substance produced from a microorganism generally considers generally available microbiological data and information about the potential toxigenicity and pathogenicity of the microorganism. Whether toxicological studies would be necessary to demonstrate the safety of the substance as manufactured would depend on what the substance is and its intended use in food.

E. GRAS Status of Certain Food Substances

We proposed to remove § 170.30(f), which expresses our intent to review the GRAS status of certain food substances. We received no comments that disagreed with our proposal to remove § 170.30(f) and are removing it as proposed.

VII. Comments on the Substitution of a GRAS Notification Procedure for the GRAS Affirmation

Petition Process

Our regulations specify procedures for us to affirm the GRAS status of the use of a food substance, whether on our own initiative (§ 170.35(a) and (b)) or on the petition of an interested person (§ 170.35(c)). We proposed to eliminate the GRAS affirmation petition process in § 170.35(c) and replace it with a GRAS notification procedure (proposed § 170.36) in which any person may notify us of a claim that a particular use of a substance is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is GRAS. Under the proposed notification procedure, we would evaluate whether the submitted notice provides a sufficient basis for a GRAS determination and whether information in the notice or otherwise available to us raises issues that lead us to question whether use of the substance is GRAS. We also proposed to presumptively convert any filed GRAS affirmation petition that is pending on the date that the petition process is replaced with a notification procedure ("pending petition") to a GRAS notice and provide an opportunity for the person who had submitted a pending petition ("affected petitioner") to amend the petition to meet the requirements for a GRAS notice.

In the 2010 notice, we discussed several issues broadly applicable to the proposed substitution of a GRAS notification procedure for the GRAS affirmation petition process (see table 3).

TABLE 3—ISSUES IN THE 2010 NOTICE BROADLY APPLICABLE TO THE PROPOSED SUBSTITUTION OF A GRAS NOTIFICATION PROCEDURE FOR THE GRAS AFFIRMATION PETITION PROCESS

Issue No.	Description of our request for comment	Reference
N/A	Our intent to use "Plain Language" tools such as pronouns in the final rule	75 FR 81536 at 81537.
2	Our reasons for tentatively concluding that the terms "conclude" and "conclusion" would be more appropriate in lieu of "determine" and "determination".	75 FR 81536 at 81538.
17	Alternative approach to administering pending GRAS affirmation petitions	75 FR 81536 at 81542–81543.

Several comments support the proposed replacement of the GRAS affirmation petition process with a GRAS notification procedure. For example, several comments support the expectation we expressed in the proposed rule (62 FR 18938 at 18941) that the substitution of a GRAS notification procedure for the GRAS affirmation petition process would result in our increased awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances. Most of these comments agree that such increased awareness could be an advantage of the notification procedure if manufacturers view our response to a GRAS notice as an incentive to participate in the program. Many comments that support the proposed replacement of the GRAS affirmation petition process with a GRAS notification procedure nonetheless raise questions about how we would administer the pending GRAS affirmation petitions. We discuss those comments in section XXIII.

In the following sections, we discuss comments that disagree with one or more aspects of our proposal to replace the GRAS affirmation petition process with a GRAS notification procedure (see, *e.g.,* Comment 24, Comment 25, and Comment 32); ask us to clarify how we generally will administer the proposed GRAS notification procedure (see, *e.g.,* Comment 31); or suggest one or more general changes to the proposed GRAS notification procedure (see, *e.g.,* Comment 27, Comment 28, Comment 30, Comment 31, and Comment 36). After considering these comments, we are replacing the GRAS affirmation petition process with a GRAS notification procedure, using the terms "conclude" and "conclusion" as described in the 2010 notice. As noted in the 2010 notice, the final rule uses Plain Language tools such as pronouns.

To improve clarity and readability we used another Plain Language tool, *i.e.,* the use of short regulatory sections that have limited subparagraph designations. To do so we redesignated the single proposed section (*i.e.,* proposed § 170.36) into several distinct, short sections of regulatory text in a newly established subpart E (GRAS Notice), with editorial changes associated with the new structure of the redesignated regulations. See table 4 for the section numbers and titles of the regulatory text in subpart E. Many provisions of the regulatory text in subpart E use singular nouns when discussing the intended use of the notified substance, *e.g.,* the definition of "GRAS notice" means a submission that informs us of your view that a specified use of a substance is not subject to the premarket approval requirements of the FD&C Act based on your conclusion that such use is GRAS. The singular term "use" is employed for a simple and consistent presentation in the regulatory text and does not mean, for example, that you are limited to notifying us about a single use of the notified substance.

We also are establishing in new subpart E the process we described in the 2010 notice for administering pending GRAS affirmation petitions. Finally, we made editorial, clarifying, and conforming changes as shown in table 29. Because the editorial changes associated with the redesignation of the notification procedure in subpart E are extensive, we do not list them in table 29.

A. Affirmation on the Initiative of the Commissioner

We proposed to amend current § 170.35(a) to clarify that the Commissioner would affirm the GRAS status of a use of a substance, rather than the substance itself, and to include a grammatical change to place § 170.35(a) in the singular. The single comment that expressly addressed this proposed amendment concurred with us on this point and we are finalizing it as proposed.

We also proposed to amend current § 170.35(a) to remove the provision that we may review the GRAS status of a substance added to food in response to a petition from an interested party. Under current § 170.35, such a petition would be submitted in accordance with the provisions of the GRAS affirmation petition process established in current § 170.35(c). We are deleting this provision as proposed. The comments we received relevant to our proposed deletion of the petition-related provision in § 170.35(a) are directed to our proposed deletion of the GRAS affirmation petition process in current § 170.35(c), and we discuss those comments in section VII.B.

B. Deletion of the GRAS Affirmation Petition Process

We proposed to eliminate the GRAS affirmation petition process in current § 170.35(c).

(Comment 24) Several comments oppose our proposal to eliminate the GRAS affirmation petition process. In general, these comments assert that we should provide manufacturers the option of seeking GRAS affirmation even though we would be establishing a new notification procedure. The comments assert that such an option is essential to support the marketing of a product in certain situations, such as when recognition of GRAS status is needed by international standard-setting bodies.

(Response 24) We acknowledge that a regulation listing the use of a substance in food could provide some support for marketing a product in certain situations, but disagree that we should retain the GRAS affirmation petition process. We note that CFSAN filed more than 600 GRAS notices during the time period 1998 through 2015 (Ref. 19), for an average of approximately 34 GRAS notices per year, including 69 GRAS notices filed during 2014 and 51 GRAS notices filed during 2015. By contrast, during that time CFSAN finalized six GRAS affirmation regulations. We believe that the ongoing submission of GRAS notices is evidence that our response to a GRAS notice can support the marketing of a food substance.

(Comment 25) Some comments assert that the proposed GRAS notification procedure would be less protective of food safety than the GRAS affirmation petition process it would replace. Some comments assert that our role in ensuring the safety of food ingredients is best carried out by a review of the data supporting the safety of the ingredient and that the public should also have access to these data. These comments also assert that the GRAS affirmation petition process, in which we conduct a review of supporting data, provides an incentive to manufacturers to fully research each substance and that removing this incentive would compromise safety. Other comments assert that the GRAS notification procedure would be less thorough than the GRAS affirmation petition process. One comment states that consumers are concerned about the safety and wholesomeness of substances added to food and criticizes the proposed rule as not being "rigorous enough" and as not creating a "meaningful process for adequately reviewing the safety of substances used in human and animal food."

(Response 25) We disagree that the notification procedure is less protective of food safety than the affirmation petition process. In the proposed rule, we stated that our response to a GRAS notice would not be equivalent to an agency affirmation of GRAS status because we would neither receive nor review the detailed data and information that support the GRAS determination (62 FR 18938 at 18951). These comments may have misinterpreted that statement to mean that we would not conduct a substantive evaluation of the summary information that we receive in a GRAS notice. This is not the case. CFSAN's 2010 experience document (Ref. 18) demonstrates that we have conducted a substantive evaluation of the GRAS notices that we received during the Interim Pilot program. For example, section III.C.1 of CFSAN's 2010 experience document describes examples of situations in which we contacted a notifier to request clarification about data and information in the notice. CFSAN's 2010 experience document also demonstrates that during the period 1998–2009 CFSAN had questions about 21 percent of GRAS notices, such that CFSAN either responded to the notifier that the submitted GRAS notice did not provide a basis for a conclusion of GRAS status or the notifier asked us to cease to evaluate the GRAS notice (see section III.B of CFSAN's 2010 experience document). Furthermore, we believe that the GRAS notification procedure provides us with greater flexibility to respond to safety concerns that may arise about a substance that is the subject of a GRAS notice, compared to a substance that is the subject of a GRAS affirmation regulation, which would require rulemaking to revoke.

We acknowledge that the term (*i.e.,* "evaluate") we use to describe our actions when we receive a GRAS notice is different from the term (*i.e.,* "review") we use to describe our actions when we receive a petition (whether a food or color additive petition or a GRAS affirmation petition). We decided to use a different term because, as already noted, the data and information we will receive in a GRAS notice (*i.e.,* summary data and discussions) are different from the data and information we receive in a petition (which generally includes the underlying data from studies described in the petition).

As discussed in Response 120, we currently make a hyperlink to an electronic copy of each GRAS notice accessible from our Internet site and, thus, the public has access to each GRAS notice. We also make our response to each GRAS notice accessible from our Internet site (see § 170.275(b), Response 115, and Response 116). We acknowledge that supporting data and information that are provided to us in the form of a petition can provide the public with ready access to such data and information (*e.g.,* through a FOIA request), but disagree that substitution of the GRAS notification procedure for the GRAS affirmation petition process has a fundamental impact on the public's access to supporting data and information, because a conclusion of GRAS status must be based on generally available data and information. Under the notification procedure, the publicly accessible GRAS notice both summarizes the available data and information and provides a list of publicly available data and information (see §§ 170.250 and 170.255). Under the GRAS affirmation petition process, we placed a copy of each publication provided by the petitioner to support a conclusion of GRAS status in the public docket for that petition, but our current practice with respect to copyrighted publications is to refer the public to the primary records (see § 20.51, Referral to primary source of records).

We cannot say whether a petition process would provide an incentive for a manufacturer to more fully research the safety of a substance before sending a GRAS notice to us. However, we advise a manufacturer who intends to submit a GRAS notice to expect a substantive evaluation of that GRAS notice by us. Likewise, we advise a manufacturer who reaches a conclusion that a substance is GRAS under the conditions of its intended use, but does not submit a GRAS notice to us, that when a substance is not GRAS under the conditions of its intended use (or is not otherwise excepted from the definition of "food additive" in section 201(s) of the FD&C Act), that use of the substance is a food additive use subject to our premarket review as mandated by the FD&C Act. In such circumstances, we can take various actions, including issuing a warning letter (which we make public on our Web site) to companies that manufacture or distribute the food additive and/or food containing the food additive; issuing a public alert; taking enforcement action to stop distribution of the food substance and foods containing it on the grounds that such foods are or contain an unlawful food additive; and issuing a declaratory order determining that the substance is not GRAS under the conditions of its intended use and is a food additive subject to section 409 of the FD&C Act. For example, as already discussed in section I.D, we recently issued a declaratory order making a final determination that there is no longer a consensus among qualified experts that PHOs are GRAS for any use in human food (80 FR 34650). As another example discussed in section I.D, we have issued warning letters informing four companies marketing caffeinated alcoholic beverages that caffeine, as used in the companies' products, is an unsafe food additive, and therefore the products are adulterated under section 402(a)(2)(C) of the FD&C Act (Ref. 10 through Ref. 13), and the companies subsequently ceased distribution of these products. Thus, we advise any manufacturer or distributor to carefully consider whether there is adequate support for concluding that a substance is GRAS under the conditions of its intended use and to submit its conclusion of GRAS status to us in the form of a GRAS notice.

(Comment 26) A few comments express skepticism that the substitution of a GRAS notification procedure for the GRAS affirmation petition process would result in our increased awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances. These comments assert that the proposed notification procedure offered a risk (*i.e.,* the risk of a publicly available "insufficient basis letter") without the potential benefit that was available under the petition process (*i.e.,* a regulation affirming GRAS status). These comments predict that, unless we modify the proposed rule substantially, we likely would have less awareness of GRAS substances under the notification procedure than we currently have under the GRAS affirmation petition process.

One comment asserts that the notification procedure would in no manner be equivalent to the GRAS affirmation petition process, and the substitution of a notification procedure for a petition process would be anything but neutral. This comment asserts that the proposed substitution of a notification process for the affirmation process would actually reduce the incentive for producers to notify FDA, because notification would invite regulatory scrutiny without requiring FDA to attest to a conclusion of GRAS status.

(Response 26) We disagree that the notification procedure we are establishing in this rule will reduce the incentive for producers to notify us. As already noted in Response 24, CFSAN has filed more than 600 GRAS notices between 1998 and 2015, for an average of approximately 34 GRAS notices per year. In contrast, as discussed in section IV.L of CFSAN's 2010 experience document (Ref. 18), between 1987 and 1996 CFSAN received a total of fewer than 100 GRAS affirmation petitions, with an average of approximately 8 GRAS affirmation petitions per year. These data support the expectation we expressed in the proposed rule that the substitution of a GRAS notification procedure for the GRAS affirmation petition process would result in our increased awareness of the composition of the nation's food supply and the cumulative dietary exposure to GRAS substances.

The comments that predict that we would need to modify the final rule substantially to achieve increased awareness of the nation's food supply did not suggest specific modifications for this purpose. However, this document discusses the changes we have made to the proposed notification procedure as a result of comments, described in this document and the 2010 notice, that raised specific issues and concerns regarding the proposed notification procedure. For example, the final rule defines the term "amendment" (§ 170.203) and expressly provides that a notifier may submit a timely amendment to address our questions (§ 170.260(a)). As another example, the final rule expressly provides that a notifier may ask us to cease to evaluate a GRAS notice (§ 170.260(b)). In addition, see Response 80 regarding our willingness to engage with a notifier to clarify particular aspects of the notice and Response 96 and Response 97 regarding comments that raise concerns about a publicly available insufficient basis letter. For a summary of the principal changes to the notification procedure in this final rule relative to the proposed rule, see table 2.

(Comment 27) One comment asks us to require the submission of a GRAS affirmation petition on a random basis for 20 percent of the GRAS notices we receive. This comment states that such a requirement would be essential in light of our concurrent proposal to broaden the types of safety information that could support GRAS status in the criteria for eligibility for classification as GRAS through scientific procedures. The comment refers to this procedure as a "verification audit" and describes a "verification audit" as a detailed evaluation of the scientific data and other technical information. The comment asks that the final rule give FDA such "verification authority" and asserts that such a verification system would give consumers greater confidence that the new notification system was not just a system of deregulation.

(Response 27) We decline this request. Both the GRAS notification procedure and the GRAS affirmation petition process that it is replacing are voluntary procedures and, thus, the comment's position that we could require a GRAS affirmation petition—on a random or any other basis—is incorrect. Moreover, we disagree that the revised criteria for eligibility for GRAS status through scientific procedures have any bearing on whether we should evaluate a conclusion of GRAS status through a notification procedure or a petition process. The revised criteria reflect the nature of substances being added to food, and the fact that the quantity and quality of scientific evidence required to demonstrate safety vary considerably depending upon the estimated dietary exposure to the substance and the chemical, physical, and physiological properties of the substance. See Response 23.

C. General Comments on the Proposed GRAS Notification Procedure

(Comment 28) Some comments ask us to require that companies notify us of a conclusion of GRAS status and assert that we have implied legal authority to require such notification. These comments express concern that potentially dangerous substances could enter the food supply without our knowledge or supervision. Other comments emphasize that the GRAS notification procedure should remain voluntary and assert that we lack express statutory authority to require companies to submit GRAS notices.

(Response 28) We agree that we lack express statutory authority to require companies to submit GRAS notices. In creating the premarket approval requirement for food additives in the 1958 amendment, Congress excluded a substance that is GRAS under the conditions of its intended use from the definition of food additive. The creation of this GRAS provision reflected Congress' determination that many substances intentionally added to food for a specific use do not need premarket review by FDA to ensure their safety, either because their safety has been established by a long history of use in food, or because their safety has been established by information that is generally available to and accepted by qualified experts, regarding the intended conditions of use of a substance in food. Subsequently, in 1997, the Food and Drug Administration Modernization Act (FDAMA) amended section 409 of the FD&C Act to require the establishment of a mandatory food contact notification program for human food. By contrast, Congress has not amended section 409 of the FD&C Act to require the establishment of a premarket GRAS notification procedure—either voluntary or mandatory.

We did not propose to require the submission to FDA of notices concerning all conclusions of GRAS status. We recognize that some comments suggest that such a requirement might be within our legal authority, even if not expressly required by the FD&C Act. We will consider these comments and our experience under this final rule in evaluating what, if any, further action is needed with respect to ensuring the safety of the food supply. However, mandating submission of GRAS notices would need to be done in a separate rulemaking to ensure adequate notice and comment.

(Comment 29) One comment notes that the proposed rule did not specifically ask members of the food industry to notify us of all conclusions of GRAS status. This comment suggests that the final rule include such a request, explaining that such a provision would help us to achieve our goal of increasing our awareness of substances added to food.

(Response 29) We view our establishment of the GRAS notification procedure in this final rule, as well as our announcement of the Interim Pilot program in the proposed rule, as an invitation to industry to submit GRAS notices to us for evaluation. See also § 170.205, entitled "Opportunity to submit a GRAS notice." The ongoing submission of GRAS notices during the Interim Pilot program demonstrates that the food industry is actively submitting GRAS notices. As already noted in Response 26, we believe that our filing of more than 600 GRAS notices for substances used in human food is evidence that we have increased our awareness of the composition of the nation's food supply and the dietary exposure to GRAS substances.

(Comment 30) Some comments ask us to require certain postmarket submissions of exposure and safety data related to all GRAS substances, to require submissions for conclusions of GRAS status that predate the final rule, and to require any notifier who "withdraws" a GRAS notice or receives an "insufficient basis letter" to notify us about any use of that substance.

(Response 30) We decline this request for the same reasons that we discuss in Response 28. See also the discussions in Response 25 and Response 35 regarding the responsibility of a manufacturer to ensure that a substance added to food complies with the FD&C Act, and the potential that we may disagree with a conclusion of GRAS status and take regulatory action against use of the food substance when we do so.

(Comment 31) Some comments ask us to clarify all the information we expect to be submitted in a GRAS notice. One comment states its opposition for the proposed GRAS notification procedure, but also states that if we implement such a program we should establish the framework and criteria for the voluntary submission of GRAS notices. Another comment asks us to include core requirements in the final rule. Another comment asks us to provide more explicit instructions concerning the level of detail necessary within the required elements of a GRAS notice.

(Response 31) Subpart E of part 170 (subpart E) establishes a comprehensive framework for the submission of GRAS notices, describing in detail "core requirements" such as the seven distinct parts of a GRAS notice. Subpart E also includes provisions that will govern what we will do when we receive a GRAS notice, as well as provisions that will govern disclosure of a GRAS notice. Section 170.30 establishes the revised criteria for eligibility for classification of the food use of a substance as GRAS.

(Comment 32) One comment expresses concern that the proposed GRAS notification procedure would be viewed as a "fast-track" option that would tempt a company that should submit a food additive petition to submit a GRAS notice instead.

(Response 32) We recognize that there is a possibility that some manufacturers of food ingredients may decide that they do not need to submit a food additive petition because they have concluded that the substance is GRAS under the conditions of its intended use; this possibility exists regardless of how we structure the GRAS notification procedure. However, a manufacturer's decision that a food additive petition is not required must be based on the extent to which the manufacturer has information both that the intended conditions of use of a substance in food are "safe," and that there is "general recognition" of that safety. In this rule, we clarify the criteria (§ 170.30) that govern when the intended conditions of use of a substance in food are more properly the subject of a food additive petition than a GRAS notice.

The record of our actions during the Interim Pilot program demonstrates that we will, when appropriate, issue an "insufficient basis letter" or a "cease to evaluate letter" signaling that a petition to obtain a regulation is more appropriate than a GRAS notice. As described in sections III.A.4 and III.N.2 of CFSAN's 2010 experience document (Ref. 18), in several cases during the Interim Pilot program the outcome of CFSAN's review of a GRAS notice was the notifier's subsequent submission of a food additive petition.

(Comment 33) One comment expresses the opinion that a GRAS notice could be an appropriate mechanism to inform us of a view that an additional use of an approved food additive is GRAS.

(Response 33) We agree, provided that the available data and information demonstrate that the criteria for GRAS status are satisfied. Whether an additional use of a food additive is GRAS depends on both whether that additional use is safe and on whether the safety of that additional use is generally recognized by qualified experts. To support a conclusion of GRAS status for the additional use of the substance, there must be evidence that qualified experts generally (not solely FDA experts who conducted a premarket review of a food additive petition) have evaluated generally available data and information about the intended conditions of use of the substance, and reached agreement that those generally available data and information establish the safety of the additional use of the substance. During the Interim Pilot program, CFSAN received several GRAS notices informing CFSAN of a conclusion that an additional use of an approved food additive is GRAS. As discussed in section III.A.4 of CFSAN's 2010 experience document (Ref. 18), CFSAN's response to these GRAS notices has been a case-by-case response that depends on the circumstances. In several cases, CFSAN had no questions about the notifier's conclusion of GRAS status for an additional use of a food additive; in one case, the GRAS notice did not support GRAS status for the additional use of the food additive, and the notifier subsequently submitted a food additive petition for the additional use of the substance.

(Comment 34) One comment suggests that the GRAS notification procedure would shift the burden of proof to FDA to demonstrate that a use of a substance is not safe or not GRAS after the substance is already on the market.

(Response 34) We disagree. Under the FD&C Act, the burden of supporting a conclusion that a substance is GRAS under the conditions of its intended use is on the proponent of this conclusion. *United States* v. *An Article of Food,* 752 F.2d 11, 15 (1st Cir. P.R. 1985). This burden of proof remains after the substance is on the market regardless of whether the proponent asks FDA to evaluate that GRAS conclusion, and our rule does not change this. By establishing a process for the submission of GRAS notices for FDA to review, our rule encourages firms to seek our evaluation of their conclusions, before they introduce the substance into the market.

(Comment 35) A few comments note that a notifier who markets a food substance before we issue our letter responding to the notice runs the risk that we may disagree with the conclusion of GRAS status. One comment expresses concern that we would take regulatory action to remove the substance from the food supply rather than discuss our concerns with the notifier.

(Response 35) The comments are correct that a notifier who markets a food substance before we issue our letter based on our evaluation of the notice runs the risk that we may disagree with the conclusion of GRAS status. (We note that a manufacturer who markets a food substance without submitting a GRAS notice runs a similar risk.) However, we make every effort to evaluate the data and information submitted on a timely basis, and in this rule we commit to responding to a GRAS notice within 180 days after filing the notice, with the option to extend an additional 90 days as needed. Because a substance that is GRAS under the conditions of its intended use is not subject to premarket review as a food additive under the FD&C Act, a notifier could decide to introduce the substance into the market without waiting for the letter; we could subsequently determine that the substance is an unapproved food additive, and we may take action to remove the substance from the food supply.

See also the discussion in Response 80. Our experience during the Interim Pilot program demonstrates that we are willing to contact a notifier to clarify particular aspects of a GRAS notice. As also discussed in Response 80, under the final rule, we intend to contact a notifier when we identify a safety concern. However, whether the purpose of the contact is to provide an opportunity to address that concern (*e.g.,* in an amendment or in a newly submitted GRAS notice), or to alert the notifier to our concerns while we prepare an "insufficient basis letter," has been, and will continue to be, a matter committed to our discretion depending on the totality of the circumstances.

(Comment 36) One comment suggests that we ask notifiers who previously received a "no questions letter" under the Interim Pilot program to review their prior submissions and align them with the requirements of the final rule.

(Response 36) We decline this suggestion. The final rule does not pose any substantially different data requirements than did the Interim Pilot program in terms of data quality and quantity to support the conclusion of GRAS status. We do not anticipate, as a general matter, the need to ask previous notifiers who received a "no questions letter" to provide any supplemental information. However, if we become aware of data or information that questions the GRAS status of the use of a substance that has been the subject of a "no questions letter," we may send the notifier a subsequent letter advising the notifier of those questions (see § 170.265(c)). Because we would make the subsequent letter readily accessible to the public (see § 170.275(b)(2)), other stakeholders would have ready access to those questions.

(Comment 37) One comment states that GRAS "determinations" must be evaluated based on adequate science and recommends that GRAS "determinations" comply with our guidance on food additive testing.

(Response 37) We agree that safe use(s) of a substance must be supported by adequate science. We do have extensive guidance on food additive testing (Ref. 31 through Ref. 35), and we agree that this guidance on food additive testing can be useful in the evaluation of the safety of a substance when the proponent of the substance seeks to demonstrate that the substance is GRAS under the conditions of its intended use. As discussed in Response 128, as resources allow we intend to revisit these scientific guidance documents to determine whether and how to modify them to clarify that our guidance on evaluating the safety of a food substance generally applies regardless of whether the substance would be used in food as a food additive or as a GRAS substance.

Recently, we issued a notice (79 FR 64603, October 30, 2014) announcing a public meeting, and requesting comments, on our intent to update our guidance entitled "Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients" (Ref. 35; commonly referred to as our "Redbook"). In that notice, we reiterated that general recognition of safety based upon scientific procedures requires the same quantity and quality of evidence as is required to approve a food additive. We also asked for comment on how we should balance the desire for transparency and consistency in risk assessment, as described in the Redbook, with the goal of flexibility in applying the most appropriate analysis for specific contexts.

(Comment 38) One comment states that the resource-intensive petition process would be reserved for ingredients not eligible to meet GRAS criteria, or those which pose questions necessitating indepth review by FDA scientists, even though the safety standard for GRAS ingredients and food additives is the same.

(Response 38) The comment is correct that a food additive petition would be required for an ingredient that is not eligible for classification as GRAS and is not otherwise excepted from the statutory definition of a food additive. We agree that indepth review of the safety of a substance under the conditions of its intended use in food by FDA scientists is necessary when there is no basis for a conclusion that the intended conditions of use have GRAS status. However, see Response 25. Our evaluation of a GRAS notice is a substantive evaluation even though we respond to a GRAS notice by letter rather than by establishing a regulation.

(Comment 39) One comment asserts that we tentatively concluded that the proposed notification procedure would allow us to direct our resources to the more significant questions about GRAS status, without further explaining what these "more significant questions" are. This comment further asserts that the obvious conclusion is that we will simply reduce the Federal layer of oversight in the interests of efficiency and in doing so ignore the history of food law, which has repeatedly shown that the public suffers when FDA declines to regulate.

(Response 39) See the actions we describe in section I.D, on PHOs and caffeinated alcoholic beverages, for examples of what we mean by "more significant questions." We disagree that directing our resources in such a manner reduces our oversight; on the contrary, such actions demonstrate that we will take appropriate steps to address concerns about the safety of substances marketed under the GRAS provision of the FD&C Act. The comment provides no basis for its assertion that the notification procedure ignores the history of food law or that the public will suffer.

(Comment 40) One comment points out that our response to a GRAS notice addresses the question of whether a particular use of a notified substance is GRAS, without limiting that question to production of that food substance by a specific manufacturer (*e.g.,* the notifier who submitted the GRAS notice). This comment asks us to require that any other food producer who uses the substance in food on the basis of a GRAS conclusion submitted to FDA in a GRAS notice meet all requirements and specifications in the submitted GRAS notice, including use of the same source for the production of the food substance.

(Response 40) The comment is correct that our response to a GRAS notice would not limit a food producer other than the notifier from relying on the submitted GRAS notice, and our response to that GRAS notice, when that food producer concludes that a substance is GRAS under the conditions of its intended use in food. The method of manufacture (including any source specified for the production of the notified substance) and specifications identified in a GRAS notice are relevant to both the identity of the substance and its safety for use in food. We advise any food producer who relies on a GRAS notice submitted by another person to carefully consider whether its production process, and/or the intended conditions of use of the notified substance, fall within the parameters, such as method of manufacture (including a specified source) and specifications, addressed by the submitted GRAS notice. We recently issued guidance to help food producers to do so. See our guidance entitled "Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives" (Ref. 6).

D. Comments on Certain Terms Used in the Proposed Regulatory Text

1. Replacing the Terms "Determine" and "Determination" With the Terms "Conclude" and "Conclusion"

In the 2010 notice, we explained our reasons for tentatively concluding that the terms "conclude" and "conclusion" would be more appropriate in lieu of "determine" and "determination" and requested comment on these terms (see Issue 2, 75 FR 81536 at 81538).

(Comment 41) Many comments support replacing the terms "determine" and "determination" with the terms "conclude" and "conclusion." One comment disagrees with changing the terms "determine" and "determination." This comment asserts that the terms "determine" and "determination" are more appropriate because a determination is made based on the sum of the total assembled data and conclusions. This comment also disagrees with changing the terms because individuals who already are involved in the GRAS notification procedure as a result of the Interim Pilot program are already familiar with the terms and meanings of "determine" and "determination."

One comment observes that the terms "determined" and "determination" are used in § 170.30 of our regulations within the context of establishing GRAS status. This comment asks us to clarify how we would apply the terms "determined," "determination," "conclude," and "conclusion" and whether we would limit how some terms apply depending on whether a substance is the subject of a GRAS notice. This comment expresses concern that such a distinction in terms could lead to a misperception that a substance that is the subject of a GRAS notice has a more authoritative and/or superior legal standing than a substance that does not.

(Response 41) We are replacing the term "determination" with "conclusion," and referring to a "conclusion of GRAS status" rather than to a "GRAS determination," throughout the regulatory text for the GRAS notification procedure. We recognize that notifiers involved with the GRAS notification procedure may be more familiar with the terms "determine" and "determination." Nevertheless, we believe that as notifiers gain more experience with the GRAS notification procedure set forth in this final rule, notifiers will adjust to using "concludes" and "conclusion."

We are making conforming changes to current regulations regarding the use of GRAS substances in food to no longer use the terms "determine" and "determination" (see the changes to §§ 170.3(k), 170.30(c)(1), and 170.30(e) in table 29). We are making these conforming changes to clarify that there would be no distinction between a conclusion of GRAS status submitted to us as a GRAS notice and a conclusion of GRAS status that remains with its proponent as an independent conclusion (formerly referred to as a "self-determination") of GRAS status.

2. The Terms "Exempt," "Exemption," and "Claim"

Several provisions in the proposed rule would use terms such as "exempt," "exemption," and "claim."

(Comment 42) Several comments object to some terms used in the proposed procedure for submitting a GRAS notice. Some comments object to proposed title for the GRAS notification procedure, *i.e.,* "Notice of a claim for exemption based on a GRAS determination." Most of these comments also object to our characterization of one of the proposed provisions (proposed § 170.36(c)(1)) as a "GRAS exemption claim." In general, these comments assert that nothing in the FD&C Act or in the legislative history of the FD&C Act supports designation of GRAS status as an "exemption." In addition, several comments object to our use of the term "claim" in various proposed provisions because our use of this term implies that we have legal authority to deny a claim or that GRAS status is not operative unless a claim is filed.

(Response 42) We have made the following editorial changes throughout the regulatory text to no longer use terms such as "exempt," "exemption," and "claim." First, we replaced the term "exempt" with the phrase "not subject to." Section 201(s) of the FD&C Act provides that a substance that is GRAS under the conditions of its intended use is not within the definition of food additive. Whether the statutory GRAS provision in section 201(s) is an "exemption," or, is an "exclusion," is not essential to this rulemaking and, thus, we need not include any variations of the term "exempt" in the final rule. Second, we replaced the term "claim" (when used as a noun) with the term "view." In the past, we have used the term "view" when describing a statement or assertion that a use of a substance is GRAS (see, *e.g.,* 62 FR 36749, July 9, 1997). Finally, we simplified the title of the regulatory text to "Generally Recognized as Safe (GRAS) Notice."

E. Comments on the Use of "Plain Language" in the Regulatory Text

In the 2010 notice, we noted our intent to use "Plain Language" tools such as pronouns in the final rule (75 FR 81536 at 81537). The use of "Plain Language" tools in government writing, now called "plain writing," is consistent with the government-wide initiative to promote transparency, public participation, and collaboration throughout the Federal Government's programs and activities as set out in "Improving Electronic Dockets on Regulations.gov and the Federal Docket Management System: Best Practices for Federal Agencies" (Ref. 22).

(Comment 43) One comment recommends that we use Plain Language throughout the regulatory text to foster greater understanding about the regulatory requirements and expectations for the notification procedure, leading to a more effective program.

(Response 43) We have used "Plain Language" tools (such as short sections and the use of pronouns) throughout the regulatory text of subpart E, which establishes the requirements for the GRAS notification procedure. See table 4 for the section numbers and titles of the redesignated regulatory text in subpart E.

TABLE 4—REDESIGNATION OF THE GRAS NOTIFICATION PROCEDURE IN SUBPART E

Section	Title
170.203	Definitions.
170.205	Opportunity to submit a GRAS notice.
170.210	How to send your GRAS notice to FDA.
170.215	Incorporation into a GRAS notice.
170.220	General requirements applicable to a GRAS notice.
170.225	Part 1 of a GRAS notice: Signed statements and certification.
170.230	Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.
170.235	Part 3 of a GRAS notice: Dietary exposure.
170.240	Part 4 of a GRAS notice: Self-limiting levels of use.
170.245	Part 5 of a GRAS notice: Experience based on common use in food before 1958.
170.250	Part 6 of a GRAS notice: Narrative.
170.255	Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.
170.260	Steps you may take before FDA responds to your GRAS notice.
170.265	What FDA will do with a GRAS notice.
170.270	Procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by FSIS.
170.275	Public disclosure of a GRAS notice.
170.280	Submission of a supplement.
170.285	Disposition of pending GRAS affirmation petitions.

VIII. Definitions Applicable to a GRAS Notice

A. Definitions We Described in the 2010 Notice

In the 2010 notice, we requested comment on definitions for the terms "amendment," "notified substance," "notifier," "qualified expert," and "supplement" (see Issue 3, 75 FR 81536 at 81538). We received several comments that generally support adding definitions for these terms, and we are establishing a section in the regulatory text of subpart E to define these and other terms (see § 170.203).

B. Definition of "GRAS Notice"

(Comment 44) Some comments express concern about the potential for confusion between the proposed GRAS notification procedure and another FDA "notification program", *i.e.*, the premarket notification program for food contact substances (in part 170, subpart D) that we established under FDAMA. These comments assert that this confusion can lead to uncertainty about the nature of the proposed GRAS notification procedure, such as with respect to market "exclusivity" for the notified substance. One comment states that the terms "GRAS notice" and "GRAS notification" appear to be used interchangeably in the 2010 notice and asks whether it is our intention to use "notice," "notification," or both terms with regard to the proposed procedure for submission of a conclusion of GRAS status for a use of a food substance.

Another comment notes that the proposed rule to establish a GRAS notification procedure was followed soon thereafter by the rulemaking to establish the premarket notification program for food contact substances as authorized by FDAMA (the FCN program; proposed rule 65 FR 43269, July 13, 2000; final rule 67 FR 35724, May 21, 2002). This comment asserts that although the proposed GRAS notification procedure and the established FCN program are distinct, industry reasonably relied on the close temporal proximity of the 1997 proposed rule to establish a GRAS "notification" procedure, and the rulemaking to establish the FCN program, as contemporaneous guidance for the meaning of the term "notification" under FDAMA. Because the FCN program provides market "exclusivity" for the food contact substance, the comment asserts that it is understandable why regulated industry would think that submitting a GRAS notice likewise implies "exclusivity" for the substance. The comment notes that FDA is not responsible for misinterpretations made by industry, but asks us to recognize this lack of transparency and clarity and remedy it in a fair and equitable manner.

(Response 44) In the proposed rule and in this final rule, we use the term "notice" as a noun to refer to the submission that you send to us and we use the term "notification" as an adjective, *e.g.*, to modify the noun "procedure." In contrast, the FCN program uses the term "notification" as a noun in addition to using the term as an adjective, consistent with FDAMA's use of the term as a noun. We continue to use the term "notification" as an adjective (*e.g.*, GRAS notification procedure) in this preamble discussion of the requirements for submitting a GRAS notice. However, in the regulatory text we only use the term "notice," and we have added a definition of the term "GRAS notice" to the regulatory text (see § 170.203).

The "exclusivity" within the FCN program is provided by section 409(h)(2)(C) of the FD&C Act. See also our implementing regulation at

§ 170.100(a), which provides that a FCN is effective for the food contact substance manufactured or prepared by the manufacturer or supplier identified in the FCN submission. There is no similar provision in the FD&C Act or our regulations providing exclusivity for a substance that is used in food based on a conclusion that the substance is GRAS under the conditions of its intended use.

C. Other Terms We Are Defining in the Rule

We are defining the abbreviation "GRAS" to mean "generally recognized as safe" so that we can use that abbreviation throughout the regulatory text without defining it in each section where it appears. To clarify how pronouns apply in the regulatory text, we also are specifying in the definition section that "you" and "your" refer to a notifier, and that "we," "our," and "us" refer to FDA.

IX. Opportunity To Submit a GRAS Notice

We proposed to provide that any person may notify FDA of a claim that a particular use of a substance is exempt from the statutory premarket approval requirements based on the notifier's determination that such use is generally recognized as safe (GRAS) (proposed § 170.36(a)). We are establishing this statement of an opportunity to submit a GRAS notice in § 170.205, with the editorial changes described in Response 41 and Response 42.

X. Comments on Administrative Procedures for Submission of a GRAS Notice

We proposed that a notice of a "GRAS exemption claim" be submitted in triplicate to a specified address (proposed § 170.36(b)). We also asked for comment on whether it would be appropriate to require or recommend that the submission include an electronic copy in addition to the three paper copies (62 FR 18938 at 18946) or, at a minimum, an electronic copy of the proposed "GRAS exemption claim" (proposed § 170.36(c)(1); final § 170.225 (part 1 of a GRAS notice).

In the 2010 notice, we described comments asking us to permit a notifier to reference a previously submitted GRAS notice to support a view that an additional use of the applicable substance is GRAS. We also discussed a coordinated evaluation process with FSIS when the use of a notified substance includes use in products subject to regulation by FSIS. (Note that the discussion in the 2010 notice referred to a "coordinated review process." As discussed in Response 25, we are using the term "evaluation" rather than "review" in connection with GRAS notices. In addition, in a Memorandum of Understanding (MOU) between FDA and FSIS (Ref. 36), we specify that we will inform the notifier in writing that the notice will also be "evaluated" by FSIS to determine the suitability of the use of the substance in the production of meat, poultry, or egg products. Given the discussion in Response 25 and the terms of the MOU with FSIS, in this document, we use the term "coordinated evaluation" rather than "coordinated review.") We asked for comment relevant to these administrative procedures (see table 5).

TABLE 5—ISSUES IN THE 2010 NOTICE RELEVANT TO PROCEDURES FOR ADMINISTERING A GRAS NOTICE

Issue No.	Description of our request for comment	Reference
4	Whether the final rule should include a provision to expressly permit a notifier to incorporate into a GRAS notice data and information that were previously submitted by the notifier, or public data and information submitted by another party, when such data and information remain in our files.	75 FR 81536 at 81538.
13	Whether a notifier who submits a GRAS notice for such a substance should provide an additional paper copy or an electronic copy of the GRAS notice that we could send to FSIS.	75 FR 81536 at 81541–81542.

Several comments support the administrative procedures that we proposed or described in the 2010 notice. For example, several comments support adding a provision to allow a notifier to incorporate information into a GRAS notice, including data and information previously submitted by the notifier and public data and information submitted by another party, because such a provision would be practical, promote administrative efficiency, or reduce paper. In the following sections, we discuss comments that disagree with one or more aspects of the administrative procedures that we proposed or described as potential modifications in the 2010 notice (see, *e.g.*, Comment 45); ask us to clarify these administrative procedures (see, *e.g.*, Comment 48 and Comment 49); or suggest one or more changes to these administrative procedures (see, *e.g.*, Comment 47). After considering these comments, we are providing that you may submit a GRAS notice either in electronic format that is accessible for our evaluation or on paper; for paper submissions, a single paper copy of a GRAS notice is sufficient.

We also are finalizing a provision to allow for incorporation into a GRAS notice of data and information as described in the 2010 notice, with clarification that the referenced data and information must be specifically identified. As discussed in the 2010 notice, the provision specifies that incorporation into a GRAS notice applies only when data and information remain in our files. We do not retain records indefinitely; rather, records may be retired to a Federal Records Center and subsequently disposed of in accordance with our Records Control Schedule.

A. How To Send a GRAS Notice to FDA

We proposed to specify in the regulatory text the address where you would send a GRAS notice. We are finalizing this administrative provision with updates to reflect the current mailing address and the editorial changes described in Response 42. See the regulatory text in § 170.210(a).

(Comment 45) One comment asserts that a single GRAS notice to either CFSAN or CVM should suffice to inform both Centers of a conclusion of GRAS status.

(Response 45) We disagree. Our regulations directed to human food are established in subchapter B of 21 CFR (*i.e.*, Food For Human Consumption, parts 100–199), whereas our regulations directed to animal food are established in subchapter E of 21 CFR (*i.e.*, Animal Drugs, Feeds, And Related Products, parts 500–599). We have separately established requirements applicable to GRAS substances for use in human food in subchapter B of 21 CFR (*e.g.*, in parts 170, 182, 184, and 186) and requirements applicable to GRAS substances for use in animal food in subchapter E of 21 CFR (*e.g.*, in parts 570, 582, and 584). We also had separately established requirements for the GRAS affirmation petition process (which the GRAS notification procedure is replacing) for substances for use in human food in subchapter B of 21 CFR (*i.e.*, in § 170.35(c)) and requirements applicable to the GRAS affirmation petition process for substances for use in animal food in subchapter E of 21 CFR (*i.e.*, in § 570.35(c)). We address food substances separately for human use and for animal use because the safety evaluation of a food substance relates to the conditions of its intended use, and the conditions of use of a substance in human food can raise different safety questions than the conditions of use of that same substance in animal food. For example, a substance containing copper can be safely used in human food and in food for many animal species, but even small amounts of copper can be toxic to sheep. As another example, FDA has affirmed that several uses of propylene glycol in human food are GRAS (§ 184.1666), but propylene glycol is known to be toxic to cats and FDA has prohibited its use in cat food (see § 589.1001). Therefore, the final rule establishes separate (albeit parallel) requirements for submission of a GRAS notice to CFSAN for the use of a substance in human food and for submission of a GRAS notice to CVM for the use of a substance in animal food.

B. Option for Submission of Electronic or Paper Copies of a GRAS Notice

(Comment 46) Most of the comments that responded to our request for comment on the submission of an electronic copy of a GRAS notice encourage us to recommend, but not require, submission of an electronic copy, explaining that an electronic copy would make our administration of the notification procedure more efficient. However, one comment notes that electronic technology may not be universally available. As discussed in Comment 47, another comment expresses concern about protection for confidential information in an electronic copy. One comment suggests that if we use an electronic means to make GRAS notices readily accessible to the public, then we should require that the submission include an electronic copy. Comments that address Issue 13 support requiring the notifier to provide an additional paper copy that we would send to FSIS as part of this procedure.

(Response 46) We agree that an electronic copy will make our administration of the GRAS notification procedure more efficient. For example, an electronic copy generated from a word processing format generally is searchable without the need for Optical Character Recognition techniques, but an electronic copy generated by scanning a paper document into "Portable Document Format" ("pdf") requires Optical Character Recognition before it can be searched electronically. Furthermore, the Government Paperwork Elimination Act of 1998 (Pub. L. 105–277, Title XVII) requires Federal agencies to give persons who correspond with these agencies the option of doing so electronically when practicable as a substitute for paper, and to use electronic authentication (electronic signature) methods to verify the identity of the sender and the integrity of the electronic content. We acknowledge that technology may not be available to every notifier and, thus, the final rule does not require the submission of an electronic copy. Instead, the final rule provides that when you submit your GRAS notice, you may do so either in electronic format that is accessible for our evaluation or on paper (see § 170.210(b)). Because you have an option to submit a GRAS notice either electronically or on paper, an electronic copy will essentially replace the need for a paper copy. In 2010, CFSAN issued draft guidance for how to transmit a submission, including a GRAS notice, in electronic format (Ref. 37).

We used electronic means to make submitted GRAS notices accessible to the public during the Interim Pilot program, and intend to continue to do so under the final rule. However, we decline the request to require that the submission include an electronic copy solely because we are doing so. We acknowledge that an electronic copy will improve the efficiency with which we make GRAS notices available to the public (see the public disclosure provisions of this rule in § 170.275). However, during the Interim Pilot program we made an electronic copy of a submitted GRAS notice available on the Internet by scanning the paper GRAS notice to create an electronic pdf document, and we intend to continue to do so when you submit a GRAS notice on paper under the final rule.

We have decided that a single copy of a GRAS notice that is submitted on paper is acceptable (rather than the three copies that we proposed to require) and have specified that a single paper copy is sufficient in the regulatory text (§ 170.210(b)). We proposed to require three copies of a submitted GRAS notice to make it easier to provide a paper copy of the GRAS notice to all members of our staff who will evaluate the GRAS notice. However, in practice during the Interim Pilot program we developed internal procedures in which we scan a GRAS notice submitted on paper to create an electronic pdf version of the GRAS notice, and we make the electronic pdf document available to all staff who will evaluate the GRAS notice. This procedure has reduced the resources needed to distribute the GRAS notice to our staff, and we intend to continue to use this procedure when we receive a GRAS notice on paper. When we coordinate our evaluation of a GRAS notice with FSIS, we send an electronic copy to FSIS and, thus, an additional paper copy for use by FSIS is not necessary.

(Comment 47) One comment expresses concern about the security of confidential information in an electronic submission. This comment asks us to allow a notifier to edit an electronic copy to remove confidential information and present that information only in the paper copy. Another comment asks us to provide the same protections that would apply to confidential information in written records to confidential information in electronic records.

(Response 47) We decline the request to allow you to edit an electronic copy of your GRAS notice such that the electronic copy would differ from the paper copy. If you have concerns about the security of confidential information in an electronic submission, you have the option to send the GRAS notice on paper (see Response 46). The protections applicable to confidential information are the same regardless of whether the information is in written or electronic form (see part 20, "Public Information"). In particular, under § 20.20(e), "Policy on disclosure of Food and Drug Administration records," the term "record" (as well as any other term used in § 20.20 in reference to information) includes any information that would be an agency record maintained by the Agency in any format, including an electronic format.

In addition, the final rule requires you to state in writing your view as to whether any of the data and information in your GRAS notice are exempt from disclosure under FOIA (*e.g.*, as trade secret or as commercial or financial information that is privileged or confidential) (see § 170.225(c)(8)). The final rule also requires that if you view any of the data and information in your GRAS notice as exempt from disclosure under FOIA, you must identify the specific data and information (§ 170.250(d)). Together, these provisions will give us notice as to whether we will need to evaluate specific data and information under the FOIA and take steps to protect applicable data and information from public disclosure.

C. Incorporation Into a GRAS Notice

(Comment 48) One comment supports adding a provision to allow a notifier to incorporate data and information into a GRAS notice as long as the notifier has explicit first-hand knowledge of the referenced files. Other comments address the limitation, discussed in the 2010 notice, that data and information that are submitted by a person other than the notifier must be public, noting that it would be difficult to prevent the use of public information by others or that incorporating such data and information into a GRAS notice would be consistent with the criteria for general recognition of safety.

(Response 48) A notifier must have sufficient knowledge of data and information submitted by another party to be able to identify the specific data and information that would be incorporated into a GRAS notice. To make this clear, the provision we are adding to the rule to allow for incorporation of data and information into a GRAS notice requires that such data and information be specifically identified. For example, we expect you to provide a specific file number (*e.g.,* for a GRAS notice or a food additive petition) that contains the referenced data and information, and to identify the specific data and information in that file (rather than to broadly incorporate into a GRAS notice the entire file without explaining which data and information to incorporate). Although you may also incorporate into a GRAS notice a "food master file" (provided that you specifically identify both the file number and the data and information in that file that you are asking us to incorporate into a GRAS notice), the regulatory text does not include "food master file" as an example of the type of file that you may reference because we do not have a regulatory definition for "food master file." See the discussion of "food master file" in Response 49.

A notifier also must have sufficient knowledge of data and information submitted by another party to be able to discuss these data and information in the narrative that is required in part 6 of a GRAS notice (see § 170.250). This narrative must explain the basis for the notifier's view that the notified substance is safe under the conditions of its intended use and that GRAS criteria—for both general availability and general acceptance—are satisfied. In other words, a GRAS notice must present the independent conclusions of the notifier regarding the basis for GRAS status, even if the data and information on which the notifier relies were submitted by another person.

Consistent with the discussion in the 2010 notice, the provision we are adding to allow for incorporation of data and information into a GRAS notice specifies that data and information submitted by another party must be "public." By "public," we mean data and information that we have provided (or would provide) in response to a request under the FOIA, or that are otherwise publicly available (*e.g.,* in a docket). Consistent with the views expressed in the comments, we see no reason to preclude you from referring us to such public information when we already have such information in our files, provided that you identify the specific data and information and the file(s) containing these data and information. We would not, for example, search our files to look for the referenced data and information. However, if you intend to incorporate into a GRAS notice data and information that were submitted by another party, and that you believe to be public information, we recommend that you explain the basis for your view that the data and information are public. If we need to evaluate the status of the data and information under the FOIA (*e.g.,* because the data and information have not previously been disclosed to the public), we may decline to file the GRAS notice until we have evaluated the status of the referenced data and information under the FOIA. Doing so would be appropriate in light of the perspective of the comments, as discussed in the 2010 notice, that the process of incorporation would be administratively efficient (75 FR 81536 at 81538) and the limited time (*i.e.,* 180 days) that we have to respond after we file a submission as a GRAS notice (see § 170.265(b)). A notifier who intends to incorporate data and information that we must evaluate under the FOIA before we determine whether the data and information can be disclosed under the FOIA may find it advantageous to request those data and information under our public information procedures (see part 20), and then either include the data and information we disclose in response to that request in the submitted GRAS notice, or refer us to administrative information identifying the completed FOIA request when asking us to incorporate the data and information into a GRAS notice.

(Comment 49) One comment states its presumption that a "food master file" is not available for public viewing, referring to a "long-standing center policy" that such files are confidential. This comment asks us to continue to provide that a "food master file" be a confidential repository for proprietary data, such as utility and manufacturing information.

(Response 49) We establish a "food master file" for a variety of reasons. For example, a person who submits a food additive petition may need us to evaluate data and information regarding a substance that the petitioner purchases from another party for use in the manufacture of the food additive. The petitioner may ask the manufacturer of that substance to provide the applicable data and information to us, and we then place the submitted data and information in a food master file. Although some or all of the data in such a food master file may be exempt from public disclosure (*e.g.,* as trade secret information or confidential commercial information), a determination of whether specific data and information in a food master file is exempt from public disclosure is based on the status of the data and information under FOIA rather than on the type of file in which we place the data and information. We do not limit the type of data and information that may be included in a food master file to proprietary data and information.

See also § 170.215 and Response 48. Data and information submitted by a party other than a notifier must be public information. If you previously submitted a food master file to us, and you view the data and information in your food master file as proprietary, you must explain in part 6 of your GRAS notice how GRAS criteria are satisfied (see § 170.250(e)).

XI. General Requirements Applicable to a GRAS Notice

The final rule specifies two general provisions applicable to a GRAS notice (see § 170.220). As discussed in Response 43, we have redesignated the single proposed section (*i.e.,* proposed § 170.36) into several distinct, short sections of regulatory text in a newly established subpart E (GRAS Notice). The first general provision specifies that a GRAS notice has seven parts, refers the user to the regulatory text for each of these parts, and specifies that you must submit the information specified in each of these parts on separate pages or sets of pages (§ 170.220 (a)). Submitting the information on separate pages or sets of pages is consistent both with the guidance we developed for preparation of a GRAS notice in electronic format (Ref. 37) and with long-standing requirements for other regulatory submissions, such as a food additive petition (see § 171.1(f)) and a health claim petition (see § 101.70(g)).

The second general provision specifies that you must include each of the seven parts; if a part is not included, you must include an explanation of why that part does not apply to your GRAS notice (§ 170.220 (b)). We added this provision because some parts of a GRAS notice (*e.g.,* Part 4 (self-limiting levels of use) and Part 5 (experience based on common use in food before 1958)) would not apply to most GRAS notices. Specifying that Parts 4 and 5 do not apply to a particular GRAS notice will make it clear that a notifier is aware of the requirements of those parts and has acknowledged that they do not apply.

XII. Comments on Part 1 of a GRAS Notice: Signed Statements and Certification

We proposed that a GRAS notice must include a dated and signed claim that a particular use of a substance is exempt from the premarket approval requirements of the FD&C Act because the notifier has determined that such use is GRAS. The proposed "GRAS exemption claim" would include: (1) The name and address of the notifier; (2) the common or usual name of the notified substance; (3) the applicable conditions of use of the notified substance, including the foods in which the substance is to be used, levels of use in such foods, and the purposes for which the substance is used, including, when appropriate, a description of the population expected to consume the substance; (4) the basis for the GRAS determination (*i.e.,* through scientific procedures or through experience based on common use in food); and (5) a statement that the data and information that are the basis for the notifier's GRAS determination are available for our review and copying at reasonable times at a specific address set out in the notice or will be sent to us upon request (proposed § 170.36(c)(1)). In the 2010 notice, we requested comment on several issues relevant to the proposed "GRAS exemption claim" (see table 6).

As discussed in Response 42, we have made editorial changes throughout the rule to replace the term "exempt" with the phrase "not subject to" and to replace the term "claim" (when used as a noun) with the term "view." In light of these editorial changes, in the remainder of this section we generally use the term "proposed signed statements" (rather than "GRAS exemption claim") when referring to the provisions that we had proposed to include in proposed § 170.36(c)(1)).

TABLE 6—ISSUES IN THE 2010 NOTICE REGARDING THE PROPOSED SIGNED STATEMENTS IN A GRAS NOTICE

Issue No.	Description of our request for comment	Reference
6a	How to best ensure that the identity and authority of the person who is signing the GRAS notice is made clear.	75 FR 81536 at 81539.
6b	Whether to require that a notifier submit a statement that to the best of his knowledge, the GRAS notice is a representative and balanced submission that includes unfavorable information, as well as favorable information, known to him and pertinent to the evaluation of the safety of the substance.	75 FR 81536 at 81539.
6b	Whether to require a notifier to certify to the statement (described in Issue 6a) regarding the representative and balanced nature of the GRAS notice.	75 FR 81536 at 81539.
7	Whether to require that the GRAS notice include the name of the notified substance, using an appropriately descriptive term, instead of the "common or usual name" of the notified substance.	75 FR 81536 at 81539.
8	Whether to explicitly require that the information submitted in the "GRAS exemption claim" exclude non-public information.	75 FR 81536 at 81539.
9b *	Whether to require that a notifier who identifies one or more trade secret(s) in the GRAS notice explain why it is trade secret information and how qualified experts could conclude that the intended use of the notified substance is safe without access to the trade secret(s).	75 FR 81536 at 81540.
9c *	Whether to require that a notifier who identifies confidential commercial or financial information in the GRAS notice explain why it is confidential commercial or financial information and how qualified experts could conclude that the intended use of the notified substance is safe without access to such information.	75 FR 81536 at 81540.
13	Whether to make our coordinated evaluation process with FSIS explicit in the final rule	75 FR 81536 at 81541–81542.

* In the 2010 notice, Issues 9b and 9c asked how qualified experts could conclude that the intended use of the notified substance is "GRAS" rather than "safe." However, the qualified experts evaluate safety rather than GRAS status; the person who is responsible for the conclusion of GRAS status considers the view of the qualified experts on safety in reaching the conclusion that GRAS criteria are satisfied. In the remainder of this document, we describe Issues 9b and 9c with respect to whether qualified experts could conclude that the intended use of the substance is "safe" rather than "GRAS."

In general, comments directed to the proposed signed statements agree that we should modify the provisions as discussed in Issues 6a, 6b, 7, 8, 9a, 9b, 9c, and 13 in the 2010 notice. In the following sections, we discuss comments that address the issues discussed in the 2010 notice (see, *e.g.,* Comment 50, Comment 51, Comment 57, Comment 58, and Comment 59); address provisions of the proposed signed statements that we did not discuss in the 2010 notice (see, *e.g.,* Comment 53); ask us to clarify how we will interpret the provisions of the proposed signed statements and potential modifications (see, *e.g.,* Comment 54 and Comment 55); or suggest one or more changes to the proposed signed statements and potential modifications (see, *e.g.,* Comment 52, Comment 56, and Comment 59). After considering these comments, we are establishing requirements for Part 1 of a GRAS notice to include certain signed statements and a certification as shown in table 7, with editorial, clarifying, and conforming changes as shown in table 29. (See § 170.225.) Table 7 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(c)(1) as § 170.225.

We did not receive comments disagreeing with the proposed requirement for a GRAS notice to: (1) Be dated and signed by a responsible official of your organization, or by your attorney or agent; (2) provide your name and address; and (3) provide the applicable conditions of use of the notified substance. Therefore, we are establishing those requirements in the rule (see § 170.225(c)(1), (2), and (4)).

See Comment 42 for our discussion of comments on the terms used in final § 170.225(c)(6), in which you inform us of your view that the notified substance is not subject to the premarket approval requirements of the FD&C Act based on your conclusion that the substance is GRAS under the conditions of its intended use; see Response 42 for the editorial changes we made in response to those comments.

TABLE 7—FINAL REQUIREMENTS FOR SIGNED STATEMENTS AND A CERTIFICATION IN PART 1 OF A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 1 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.225(a)	170.36(c)(1)	N/A	Must be dated and signed by a responsible official of your organization, or by your attorney or agent.	N/A.
170.225(b)	N/A	8	Must not include any information that is trade secret or confidential commercial information.	Makes an exception for § 170.225(c)(8), which requires you to state your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the FOIA.
170.225(c)(1)	N/A	N/A	Informs us that you are submitting a GRAS notice in accordance with subpart E.	N/A.
170.225(c)(2)	170.36(c)(1)(i)	N/A	Provides the name and address of your organization.	N/A.
170.225(c)(3)	170.36(c)(1)(ii)	7	Provides the name of the notified substance, using an appropriately descriptive term.	N/A.
170.225(c)(4)	170.36(c)(1)(iii)	N/A	Describes the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the substance.	Uses the term "subpopulation" rather than "population".
170.225(c)(5)	170.36(c)(1)(iv)	N/A	Informs us of the statutory basis for your conclusion of GRAS status (*i.e.,* through scientific procedures or through experience based on common use in food).	• Specifies that a conclusion of GRAS status through scientific procedures is in accordance with both § 170.30(a) and (b). • Specifies that a conclusion of GRAS status through experience based on common use in food is in accordance with both § 170.30(a) and (c).
170.225(c)(6)	170.36(c)(1)	2	States your view that the notified substance is not subject to the premarket approval requirements of the FD&C Act based on your conclusion that the substance is GRAS under the conditions of its intended use.	See Response 42.
170.225(c)(7)	170.36(c)(1)(v)	N/A	States your agreements regarding making data and information available to us upon our request.	You agree to a procedure in which we can access data and information "during customary business hours" rather than "at reasonable times".
170.225(c)(8)	N/A	9	States your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the FOIA.	N/A.
170.225(c)(9)	170.36(c)(4)	6b	Certifies that, to the best of your knowledge, your GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance.	Specifies that your GRAS notice is "complete" in addition to "representative" and "balanced".
170.225(c)(10)	170.36(c)(1)	6a	States both the name and position or title of the person who signs the GRAS notice.	N/A.

TABLE 7—FINAL REQUIREMENTS FOR SIGNED STATEMENTS AND A CERTIFICATION IN PART 1 OF A GRAS NOTICE—Continued

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 1 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.225(c)(11)	N/A	13	When applicable, states whether you: (1) Authorize us to send any trade secrets to FSIS; or (2) ask us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS.	We added a statement communicating how you want us to handle trade secret information in a copy of a GRAS notice that we send to FSIS.

A. Exclusion of Trade Secret and Confidential Commercial Information From the Signed Statements

(Comment 50) Several comments support a provision specifying that information submitted in the signed statements exclude non-public information. One of these comments states that the information in the signed statements should be publicly disclosed because public disclosure is critical to the continued success of the GRAS program, and that for the use of a substance to be "generally recognized as safe" the data and research supporting a conclusion of GRAS status must be available for public view. Other comments disagree that non-public information should be excluded from the signed statements and assert that the final rule should allow for the submission of limited amounts of non-public information at the discretion of the notifier or when necessary to clarify the safety of the notified substance for the purposes of our evaluation. These comments emphasize we should take care to remove such non-public information from any public disclosure or, or at a minimum, discuss or clear our intent to disclose non-public information with the notifier before disclosing it.

(Response 50) Some of these comments appear to misinterpret the reach of our request for comment in Issue 8 in the 2010 notice. We narrowly directed Issue 8 to the signed statements that would provide the name and address of the notifier; the name of the notified substance; the applicable conditions of use of the notified substance; the statutory basis for the conclusion of GRAS status; and agreement to make the data and information that are the basis for the notifier's conclusion of GRAS status available for our review and copying. The signed statements provide administrative information rather than safety information and, as discussed in the 2010 notice, we extract notice-specific information from the signed statements for the purpose of informing the public about GRAS notices that we are evaluating. However, some comments seem to be addressing the issue of whether other sections of a GRAS notice (*e.g.,* Part 2 of a GRAS notice (in which a notifier describes the method of manufacture of the notified substance) and Part 6 of a GRAS notice (in which a notifier discusses the safety of the notified substance)) can include non-public information.

Consistent with our request for comment in Issue 8, the final rule specifies that a notifier must not include any information that is trade secret or confidential commercial information in Part 1 of a GRAS notice, except in the statement in § 170.225(c)(8) (see § 170.225(b) and the discussion of § 170.225(c)(8) in Response 57). This provision does not preclude a notifier from including non-public information in other parts of a GRAS notice. However, if a notifier views any submitted data and information as exempt from disclosure under the FOIA then that notifier must identify the specific data and information, and explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to those data and information (see § 170.250(d) and (e)). Section 170.250(d) and (e) is consistent with the criteria for eligibility for classification as GRAS, because: (1) The criteria provide that general recognition of safety may be corroborated by unpublished information; and (2) the notifier has a burden to explain how GRAS criteria are satisfied given that certain data and information in the GRAS notice are trade secret or confidential commercial information.

See section XIII.B for a discussion of comments regarding including non-public information in part 2 of a GRAS notice (particularly with respect to the method of manufacture). Regarding whether we would "clear our intent" to disclose non-public information with the notifier before disclosing it, see Response 70. Regarding how we treat non-public information in a GRAS notice, see section XXI regarding the provisions of the final rule regarding public disclosure of information in a GRAS notice. Under § 170.275(c), we will disclose information that is not exempt from public disclosure in accordance with part 20.

B. Name of the Notified Substance, Using an Appropriately Descriptive Term

(Comment 51) Some comments agree that the signed statements should identify the name of the notified substance using an "appropriately descriptive term" instead of the "common or usual name," and also agree with our statement in the 2010 notice that the "appropriately descriptive term" may be the same as the common or usual name of the substance in some circumstances (75 FR 81536 at 81539). One comment disagrees and asks us to continue to specify that the signed statements in a GRAS notice identify the name of the notified substance using the common or usual name of the notified substance. This comment recommends that a notifier work with us to establish the common or usual name of the notified substance if the common or usual name is not known or well defined. This comment also asks us to include the common or usual name of the notified substance in any "no questions letter" from us to make the common our usual name clear to the public. A few comments support requiring that the signed statements include both the common or usual name of the notified substance, as well as an appropriately descriptive term for the notified substance. One comment asks us to continue the practice, described in the 2010 notice (75 FR 81536 at 81539), of reminding notifiers that our response to a GRAS notice should not be considered an endorsement for any given term for the purpose of complying with the labeling provisions of the FD&C Act.

(Response 51) The final rule requires that you provide the name of the notified substance, using an appropriately descriptive term, in Part 1 of your GRAS notice (§ 170.225(c)(3)). The appropriately descriptive term may be the same as the common or usual name of the substance under our labeling regulations (see 21 CFR 102.5). We decline the request to use resources that we are directing to the evaluation of the safety and regulatory status of food substances under sections 201 and 409 of the FD&C Act to also address the labeling requirements of the FD&C Act given the limited time (*i.e.,* 180 days) that we have to respond (see § 170.265(b)). You may consult with our staff in operating divisions that address the labeling requirements of the FD&C Act, currently CFSAN's Office of Nutrition and Food Labeling (for human food); however, doing so would be a separate process from the GRAS notification procedure. (See section XXV.C for contact information for CVM.)

C. Intended Conditions of Use of the Notified Substance

We did not receive comments disagreeing with the proposed requirement for the signed statements in a GRAS notice to include the applicable conditions of use of the notified substance, including the foods in which the substance is to be used, levels of use in such foods, and the purposes for which the substance is used, including, when appropriate, a description of the population expected to consume the substance, and we are establishing this requirement in the final rule (see § 170.225(c)(4)). As noted in table 29, the final rule refers to the "intended conditions of use" rather than the "applicable conditions of use" for consistency with other provisions in the rule. The final rule also uses the term "subpopulation" rather than "population" to provide more context about when it would be appropriate to specify the expected consumers of a food. Most foods are broadly available to all consumers; a few are more specifically targeted to particular subpopulations, such as persons with specific dietary needs (such as persons on liquid diets or persons with conditions like phenylketonuria), infants consuming infant formula, and persons seeking alternatives to commonly used food ingredients (such as persons on a gluten-free diet).

D. Statutory Basis for the Conclusion of GRAS Status

(Comment 52) Some comments ask us to modify the rule to provide that the statutory basis for a conclusion of GRAS status may be through scientific procedures, through experience based on common use in food, or through both scientific procedures and experience based on common use in food. These comments assert that many conclusions of GRAS status are based on both statutory criteria.

(Response 52) We disagree that this modification is needed. The final rule does not prevent you from basing your conclusion of GRAS status on both statutory criteria. Importantly, if you assert that your conclusion of GRAS status is based on both statutory criteria, you must fully support each conclusion and address all requirements of the rule regarding each conclusion; partial support for each of the two statutory criteria for a conclusion of GRAS status is not adequate. You could not, for example, assert that a substance is GRAS under the conditions of its intended use through scientific procedures, but "fill in data gaps" by also asserting that the substance was commonly used in food before 1958. Likewise, you could not assert that a substance is GRAS under the conditions of its intended use through experience based on common use in food if you cannot provide evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to January 1, 1958.

These comments highlight the importance of fully supporting a conclusion of GRAS status through each of the statutory criteria. Because the general criteria in § 170.30(a), as well as the specific criteria in § 170.30(b) or (c), must be satisfied to support a conclusion of GRAS status, the final rule specifies that a conclusion of GRAS status through scientific procedures is in accordance with both § 170.30(a) and (b) and that a conclusion of GRAS status through experience based on common use in food is in accordance with both § 170.30(a) and (c).

E. Agreement To Make Data and Information Available Upon Request

(Comment 53) Some comments recommend that there be a means for us to request non-public information if we deem it necessary for our evaluation of the intended conditions of use of the notified substance, provided that the information can be considered as confidential and protected from disclosure.

(Response 53) These comments appear to misinterpret the reach of the proposed requirement to agree to provide us access to data and information that a notifier relies on to support a conclusion of GRAS status. Some of the data and information that we may ask to see during our evaluation of a GRAS notice may be "public" data and information in that it would be data and information that we would provide in response to a request under the FOIA (see Response 48), even though it may not have been disseminated to the public (*e.g.,* in the scientific literature or on the Internet (*e.g.,* when a science-based organization uses the Internet to disseminate scientific or technical information or recommendations)). If we receive data and information that are non-public, such data and information would be protected from public disclosure in accordance with part 20.

(Comment 54) One comment states that the phrase "at reasonable times" refers not only to hours of a day, but also to a reasonable amount of time following the submission of a GRAS notice. This comment recommends that "several years (for example, five years)" after submission of a GRAS notice would be a reasonable time for notifiers to retain such data and information in their active files.

(Response 54) By "at reasonable times," we meant the time of day that we would have access to data and information you retained but did not include in your GRAS notice. To clarify that the requirement relates to the time of day rather than to the timeframe for retaining the data and information, the final rule specifies that you agree to a procedure in which we can access data and information "during customary business hours" rather than "at reasonable times."

As previously discussed (62 FR 18938 at 18951), we may, at some point after our response to a GRAS notice, receive additional information about a notified substance that raises questions about the safety of that substance. To address this possibility, the rule specifies that we will send you a subsequent letter about your GRAS notice if circumstances warrant (see § 170.265(c)). Although the rule does not specify any timeframe to retain the data and information that support your conclusion of GRAS status, preservation of the data and information that are the basis for the conclusion of GRAS status represents prudent practice for those who claim an exclusion from a statutory requirement regardless of whether the person subsequently notifies us (62 FR 18938 at 18947).

(Comment 55) One comment asks us to clarify that electronic records are acceptable for documenting the data and information that support a conclusion of GRAS status.

(Response 55) Electronic records are acceptable for documenting the data and information that support a conclusion of GRAS status. If we ask you to send us such data and information for a notified substance that would be used in human food, we recommend that you do so by following the instructions in CFSAN's guidance entitled "Guidance for Industry: Providing Regulatory Submissions in Electronic or Paper Format to the Office of Food Additive Safety" (Ref. 37), which includes instructions for making an electronic submission through our Electronic Submission Gateway, as well as on media that we can access on our network computers. CFSAN's procedures for making an electronic submission through our Electronic Submission Gateway use a form that CFSAN developed for a GRAS notice when a substance would be used in human food (*i.e.*, Form FDA 3667) (Ref. 38). Form FDA 3667 prompts a notifier to include certain elements of a GRAS notice in a standard format. The form, and elements that would be prepared as attachments to the form, may be submitted in electronic format via the Electronic Submissions Gateway, as electronic files on physical media, or in paper format. At this time, we cannot accept media such as thumb drives, which can present a security risk.

(Comment 56) One comment asks us to develop criteria for the required documentation underlying industry conclusions of GRAS status.

(Response 56) We are not establishing criteria in the rule for the documentation a notifier would have regarding a conclusion of GRAS status. Regardless of whether a person who concludes that a use of a food substance is GRAS notifies us, the applicable documentation would address the safety of the substance as described in the definition of "safe" or "safety" (see § 170.3(i)); as applicable, the definition of "common use in food" (see § 170.3(f) and/or the definition of "scientific procedures" (§ 170.3(h)); and the criteria for general recognition of safety (see § 170.30)).

F. Statements and Any Applicable Explanation Regarding Data and Information That a Notifier Views as Exempt From Disclosure Under FOIA

In Issue 9 in the 2010 notice (75 FR 81536 at 81539–81540), we discussed three issues regarding confidential data and information that are included in a GRAS notice. See table 8. Most of the comments that address Issue 9 address Issue 9a, particularly with respect to how we would protect trade secret or confidential commercial information from public disclosure. See sections XIII.B and XXI.C for a discussion of those comments, and our response to those comments. In the following paragraphs, we discuss comments on Issues 9b and 9c, and respond to those comments.

TABLE 8—ISSUES IN THE 2010 NOTICE REGARDING CONFIDENTIAL DATA AND INFORMATION IN A GRAS NOTICE

Issue No.	Description of our request for comment	Reference
9a	Whether the final rule should stipulate that the method of manufacture exclude any trade secrets, as we proposed.	75 FR 81536 at 81539–81540.
9b	Whether to require that a notifier who identifies one or more trade secret(s), as defined in § 20.61(a), in the GRAS notice explain why it is trade secret information and how qualified experts could conclude that the intended use of the notified substance is safe without access to the trade secret(s).	75 FR 81536 at 81539–81540.
9c	Whether to require that a notifier who identifies confidential commercial or financial information, as defined in § 20.61(b), in the GRAS notice explain why it is confidential commercial or financial information and how qualified experts could conclude that the intended use of the notified substance is safe without access to such information.	75 FR 81536 at 81539–81540.

(Comment 57) One comment supports the recommendation we made in the proposed rule for a notifier who considers that certain information in a submission should not be available for public disclosure to identify as confidential the relevant portions of the submission for our consideration (62 FR 18938 at 18952). Those comments that address Issues 9b and 9c agree with the outcome of our discussion, in the 2010 notice, that we should require that a notifier who identifies a trade secret or confidential commercial information explain why it is a trade secret or confidential commercial information and how qualified experts can conclude that the use of a substance is safe without access to the trade secret or confidential commercial information.

(Response 57) The final rule requires a notifier to state his view as to whether any of the data and information in Parts 2 through 7 of a GRAS notice are exempt from disclosure under the FOIA (*e.g.*, as trade secret or as commercial or financial information that is privileged or confidential) (§ 170.225(c)(8)). Requiring this statement in Part 1 of a GRAS notice will give us notice as to whether we will need to evaluate specific data and information under the FOIA and take steps to protect applicable data and information from public disclosure. See also § 170.250(d), which requires that Part 6 of a GRAS notice (a narrative) identify specific data and information that a notifier views as exempt from disclosure under the FOIA. Whereas Part 1 of a GRAS notice only requires that the signed statements in a GRAS notice state the notifier's view as to whether any of the data and information in Parts 2 through 7 of a GRAS notice are exempt from disclosure under the FOIA, in Part 6 of a GRAS notice the notifier would specifically identify the applicable data and information.

During the Interim Pilot program, we sometimes received a curriculum vitae (*e.g.*, of a GRAS panel member) containing personal privacy information that we needed to redact before we could make the GRAS notice available to the public. The rule does not require that a notifier submit such information, and redaction of unnecessary privacy information takes resources that we would otherwise use to evaluate the GRAS notice. We ask that notifiers exclude personal privacy information from a GRAS notice whenever possible. If a notifier does include such information, in Part 1 of a GRAS notice the notifier should state his view that the GRAS notice contains personal privacy information. In Part 6 of a GRAS notice, the notifier should identify the personal privacy information.

G. Certification Statement

(Comment 58) Several comments support a requirement for a GRAS notice to include a certification statement similar to the certification statement that had been required in a GRAS affirmation petition. One comment agrees that the notifier should submit a statement that the notice is a representative and balanced submission, but does not agree that the notifier needs to certify the statement.

(Response 58) The final rule requires a certification statement as described in the 2010 notice, with one modification (see § 170.225(c)(9)). We added that the statement certify that the GRAS notices is "complete" in addition to "representative" and "balanced," to emphasize your responsibility to identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with a conclusion of GRAS status, regardless of whether those data and information are generally available (see the requirements of the narrative in Part 6 of a GRAS notice (§ 170.250, in particular § 170.250(c))). The certification is appropriate and necessary to underscore your legal responsibility for the conclusion of GRAS status. As discussed in the 2010 notice, the specific text of the certification statement that you must include in a GRAS notice is consistent with the specific text of the certification statement in the GRAS affirmation petition process that the notification procedure is replacing. The use of certification statements has become routine in other submissions to FDA for food programs (see, *e.g.,* the certification statement in Part V of Form FDA 3480 (for a food contact notification submission) (Ref. 39); and the certification statement in Section 13 of Form FDA 3537 (for registration of a food facility) (Ref. 40)).

By "complete," we also mean that your GRAS notice identifies, and places in context, unpublished data and information that you believe corroborate GRAS status. For example, if you conduct six toxicology studies, but only publish three of the studies, it may be that you consider the remaining three studies to be corroborative of safety. As an example, it may be that you were dissatisfied with the study design of one study, repeated that study with an improved study design, and published the study with the improved study design. If you consider that the findings of the unpublished studies corroborate safety, even if they do not establish it, a "complete, representative, and balanced" submission would briefly describe the unpublished studies. In addition, we expect that you would describe, and place in context, unpublished data and information if you consider that the findings of the unpublished data and information warrant sharing with any "GRAS panel" that you convene. See also the discussion in Response 69 and Response 78.

(Comment 59) One comment asks us to specify that the statement include the date the statement was certified.

(Response 59) The rule requires that Part 1 of a GRAS notice be dated and signed by a responsible official of your organization, or by your attorney or agent (see § 170.225(a)). The certification statement is included in Part 1 of the GRAS notice; it is not necessary to date each statement included in Part 1.

H. Person Signing Part 1 of the GRAS Notice

(Comment 60) Several comments support a provision to require a GRAS notice to clearly identify the person signing the GRAS notice, such as by printing or stating the name and the title of the person signing the GRAS notice.

(Response 60) The final rule requires you to state both the name and position or title of the person who signs the GRAS notice (see § 170.225(c)(10)).

I. Authorization for FDA To Send Trade Secret Information to FSIS

In the 2010 notice, we described some of the terms of a MOU, between FDA and USDA's FSIS, that provides for a coordinated evaluation process with FSIS when the intended conditions of use of a notified substance include use in a product or products subject to regulation by USDA under statutes that it administers (75 FR 81536 at 81541–81542); in 2015 we amended that MOU to include more details about the procedures FDA and FSIS will follow to do so (Ref. 36). We also asked for comment on whether to make our coordinated evaluation process with FSIS explicit in the final rule (see Issue 13, 75 FR 81536 at 81541–81542).

In accordance with our public information regulations in § 20.85 (Disclosure to other Federal government departments and agencies), we can share confidential commercial information with another Federal agency pursuant to a written agreement that the record will not be further disclosed. The amended MOU between FDA and USDA's FSIS now provides for FDA to share with FSIS confidential commercial information in a submission such as a GRAS notice (Ref. 36). We generally cannot share trade secret information with other Federal agencies under section 301(j) of the FD&C Act (21 U.S.C. 331(j)), and therefore we would need your authorization to share this information with FSIS. For efficiency in administering the coordinated evaluation of a GRAS notice with FSIS, we have added a requirement for a notifier who submits a GRAS notice that we would send to FSIS to include in part 1 of the GRAS notice a statement as to whether the notifier: (1) Authorizes us to send any trade secrets to FSIS; or (2) asks us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS (see § 170.225(c)(11)). Under the provisions that make the coordinated evaluation of a GRAS notice with FSIS explicit, we will exclude any trade secrets unless you have authorized us to send trade secret information to FSIS (see § 170.270). These provisions will enable us, with your authorization, to share a GRAS notice that includes trade secret information with FSIS without first redacting the GRAS notice to remove the trade secret information and, thus, will reduce the time it takes for us to provide FSIS with a copy of the GRAS notice. These provisions also will clarify your expectations regarding whether we should share trade secret information with FSIS and, thus, require us to redact the trade secret information from the copy we send to FSIS when consistent with your express wishes.

Note that our rule establishing the requirements of the GRAS notification procedure does not specify the data and information that FSIS will need to evaluate whether the intended use of the notified substance complies with applicable statutes and regulations, or, if not, whether the use of the substance would be permitted in products under FSIS jurisdiction under specified conditions or restrictions. We recommend that you contact the appropriate staff at FSIS regarding the data and information that FSIS will need you to provide. FSIS provides contact information for its programs on its Web site (Ref. 41).

XIII. Comments on Part 2 of a GRAS Notice: Identity, Method of Manufacture, Specifications, and Physical or Technical Effect

We proposed to require that a GRAS notice include detailed information about the identity of the notified substance, including, as applicable, its chemical name, Chemical Abstracts Service (CAS) Registry Number, Enzyme Commission number, empirical formula, structural formula, quantitative composition, method of manufacture (excluding any trade secrets and including, for a substance of natural biological origin, source information such as genus and species), characteristic properties, any content of potential human toxicants, and specifications for food-grade material (proposed § 170.36(c)(2)). In the 2010 notice, we requested comment on several issues relevant to the proposed requirements for detailed information about the identity of the notified substance (see table 9).

TABLE 9—ISSUES IN THE 2010 NOTICE REGARDING THE PROPOSED REQUIREMENTS FOR DETAILED INFORMATION ABOUT THE IDENTITY OF THE NOTIFIED SUBSTANCE

Issue No.	Description of our request for comment	Reference
9a	Whether the final rule should continue to stipulate that the method of manufacture exclude any trade secrets, as proposed.	75 FR 81536 at 81539–81540.
10a	What scientific information would be sufficient to identify the biological source	75 FR 81536 at 81540.
10b	Whether to require that information about the identity of the notified substance specify any known toxicants that could be in the source.	75 FR 81536 at 81540.
10c	Whether the final rule should address, as part of identity, particle size and other chemical and physical properties that may be used to characterize engineered materials.	75 FR 81536 at 81540.

Some comments support the proposed requirements, with the potential modifications described in the 2010 notice, without change. For example, most of the comments that address the issue of scientific information sufficient to identify a biological source support requiring both taxonomic information and the part of any animal or plant used as a source. As another example, several comments that address the issue of scientific information sufficient to identify a biological source support requiring that this information specify toxicants that could be in the source.

Most of the comments regarding our proposal to require that a GRAS notice include detailed information about the identity of the notified substance address the issues discussed in 2010 notice. In the following sections, we discuss these and other comments. After considering these comments, we are establishing requirements for Part 2 of a GRAS notice to include information about the identity, method of manufacture, specifications, and physical or technical effect of the notified substance as shown in table 10, with editorial, clarifying, and conforming changes as shown in table 29. (See § 170.230). Table 10 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(c)(2) as § 170.230.

TABLE 10—FINAL REQUIREMENTS FOR DETAILED INFORMATION IN PART 2 OF A GRAS NOTICE ABOUT THE IDENTITY OF A NOTIFIED SUBSTANCE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 2 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.230(a)(1)	170.36(c)(2)	N/A	Must include scientific data and information that identifies the notified substance.	N/A.
170.230(a)(1)	170.36(c)(2)	10a	Must include data and information sufficient to identify a biological source of a notified substance.	• Must provide taxonomic information at the sub-species level (*e.g.*, variety, strain) in addition to genus and species. • Must specify the part of any plant or animal used as the source.
170.230(a)(2)	170.36(c)(2)	10b	Must include data and information sufficient to identify any known toxicants that could be in the source.	N/A.
170.230(b)	170.36(c)(2)	9a	Must include the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured.	• No longer requires that the method of manufacture exclude any trade secrets. • Requires "sufficient detail to evaluate the safety of the notified substance as manufactured" rather than "detailed information."
170.230(c)	170.36(c)(2)	N/A	Must include specifications for food-grade material.	N/A.
170.230(d)	N/A	N/A	When necessary to demonstrate safety, must include relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.	New requirement based on comments that addressed experience during CVM's Interim Pilot program (see section XXV.E).

A. Scientific Information About the Identity of a Notified Substance

1. Scientific Information Sufficient To Identify a Biological Source

(Comment 61) One comment asserts that the scientific information, beyond the standard taxonomic information, that is sufficient to identify a biological source for a notified substance should be determined on a case-by-case basis consistent with established practice and publicly available guidance. Another comment asserts that identifying the source organism by the genus and species (without additional information such as strain or variety) is sufficient when the notified substance is an enzyme preparation produced by a microorganism. However, this comment also asserts that if safety concerns for a specific genus and species have been addressed (*i.e.,* by genetic modification to remove a characteristic of concern) for a specific strain within that species then information about the strain would be appropriate. This comment emphasizes that the description of the source of a biological material should be based on the safety of that source and consider all relevant information related to safety.

(Response 61) The information, beyond the standard taxonomic information, that we discussed in the 2010 notice is consistent with established practice (see section III.J.1 of CFSAN's 2010 experience document (Ref. 18)) and the final rule specifies that when the source of a notified substance is a biological material, your GRAS notice must include both taxonomic information (*e.g.,* genus, species), including as applicable data and information at the sub-species level (*e.g.,* variety, strain) and the part of any plant or animal used as the source (see § 170.230(a)(2)). We agree that the specific scientific information, beyond the standard taxonomic information, that is sufficient to identify a biological source is determined on a case-by-case basis, and section III.J.1 of CFSAN's 2010 experience document demonstrates that the specific scientific information included in a GRAS notice to describe a biological source varied on a case-by-case basis. For example, when the notified substance was derived from a microorganism, the notifier specified a particular strain or subspecies or stated the strain was a nontoxigenic and nonpathogenic strain; when the notified substance was derived from a plant, the notifier identified the specific part(s) of the plant used as the starting material, such as fruit, seeds or seed husks, expressed oil, flowers, roots, leaves, pulp, wood, or bark. However, we disagree that we should use guidance, rather than the regulatory text of this rule, to describe the types of data and information that are necessary to sufficiently identify the biological source because the types of information we are specifying are necessary—rather than merely recommended—information. For example, data and information at the sub-species level (*e.g.,* variety, strain) is necessary for source microorganisms because so many microorganisms (*e.g., Escherichia coli* and *Saccharomyces cerevisiae*) have multiple strains, and although some strains are both non-toxigenic and non-pathogenic, others are not. For example, there are several pathogenic strains of *Saccharomyces cerevisiae,* even though nonpathogenic strains are commonly used in food and in the production of enzyme preparations. As another example, both *Aspergillus oryzae* and *Aspergillus niger* naturally produce mycotoxins, but strains that do not produce mycotoxins have been developed and are used for production of enzyme preparations. In addition, for phage production some host strains have been pathogens (*e.g., Listeria monocytogenes*) and produce toxins. Likewise, data and information about the part of a plant used as a source is necessary because some plants that have edible parts also secrete toxins in non-edible parts. For example, the leaf stalks (petioles) of rhubarb (*Rheum rhaponticum*) are edible, but the leaves contain notable quantities of oxalic acid. As another example, the leaves and stems of tomato (*Solanum lycopersicum*) contain solanine.

We agree that the description of a biological source should be based on the safety of that source and consider all relevant information related to safety. The regulatory text requires taxonomic information beyond genus and species, such as variety or strain, "when applicable" for a source microorganism such as those used to produce enzyme preparations. Examples of when information such as variety or strain would be applicable are those microbial sources, such as some fungi, for which there are multiple strains or subspecies that have different properties with respect to the ability to produce toxins, antibiotics, or other substances that are not suitable for use in food.

(Comment 62) One comment asks us to specify that information identifying a substance derived from a biological source must include the breed of animal or plant.

(Response 62) During the Interim Pilot program we did not evaluate any GRAS notices in which the breed of an animal or plant source was a taxonomic descriptor necessary to sufficiently identify that animal or plant source. Therefore, although breed may be an appropriate taxonomic descriptor in some circumstances, the circumstances are rare enough that we have not seen it as necessary information in more than 15 years. Therefore, we are not specifying it as an example of applicable taxonomic information in the rule. In a specific circumstance where breed is necessary to adequately identify a particular animal or plant source, and you do not specify the breed, we intend to ask you to amend your GRAS notice to identify the breed.

(Comment 63) One comment asks us to address substances produced from microorganisms, particularly bioengineered microorganisms. This comment explains that the development of a production microorganism through bioengineering is, for the most part, highly confidential and cannot be disclosed publicly. In addition, the production microorganism often is modified on an ongoing basis, *e.g.,* to improve yield. This comment asks us to specify the point at which subsequent modification of a production microorganism would trigger submission of a new GRAS notice and notes that in some cases subsequent modification of a production organism could be incorporated into the original GRAS notice by "amendment" or by reference. This comment also asserts that submission of a new GRAS notice should not be needed in the case of safe strain lineage as described in the scientific literature (Ref. 42).

Another comment asks us to specify that information identifying a substance derived from a biological source must specify whether the plant or animal is genetically engineered or cloned.

(Response 63) We recommend that notifiers consult our guidance entitled "Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that Are Color Additives" (Ref. 6). That guidance lists a change in the source microorganism (including a change in strain) used for a food substance derived from fermentation of a microorganism as an example of a significant manufacturing process change. Whenever there has been a significant manufacturing process change for a food substance that is the subject of a previous conclusion of GRAS status, the guidance recommends that the manufacturer consider whether the GRAS status of the use of the food substance would be affected; consult with us regarding the conclusions about the impact of the significant manufacturing change on the safety and regulatory status of the use of the food substance; and make an appropriate regulatory submission to us as circumstances warrant. In the specific circumstance of a production microorganism that is modified on an ongoing basis, a modification that results in a new strain would no longer fall within the description of the source, which must include information at the sub-species level (see § 170.230(a)(2)(i)). If a notifier concludes that a modification that results in a new strain has no impact on the conclusion of GRAS status, one approach could be to submit a supplement to the GRAS notice. Doing so would be consistent with CFSAN's 2010 experience during the Interim Pilot program. See section IV.J of CFSAN's 2010 experience document (Ref. 18), in which CFSAN discusses a GRAS notice in which a notifier consulted with CFSAN about mechanisms to inform CFSAN about its conclusion that additional uses of the notified substance are also GRAS. The notifier supplemented its original GRAS notice with a letter informing CFSAN of the additional conclusion of GRAS status and CFSAN issued a second "no questions letter" to the notifier as additional correspondence.

We decline the request to require that information identifying a substance derived from a biological source specify whether the plant or animal is "genetically engineered" or "cloned." We consider that the more general requirement to identify a biological source at the sub-species level is adequate to identify the source. In practice during the Interim Pilot program, notifiers routinely informed us about the use of such techniques in describing production microorganisms, particularly for GRAS notices about the intended conditions of use of enzyme preparations. (See, *e.g.,* the list of enzyme preparations in section IV.N of CFSAN's 2010 experience document (Ref. 18).) The source microorganisms for several of the listed enzyme preparations were developed using bioengineering techniques.

When confidential data and information about the development of a production microorganism through bioengineering are necessary to provide evidence that a notified substance produced from that production organism is safe under the conditions of its intended use, the use of the notified substance would not satisfy GRAS criteria. See the discussion in Response 69, where we explain that it may be possible to explain that confidential information (whether included in a GRAS notice, or provided privately to a GRAS panel) is corroborative of safety, rather than necessary to demonstrate safety, if, for example, the method of manufacture included in a GRAS notice meets the requirements of the rule to provide sufficient detail to evaluate the safety of the notified substance as manufactured. Alternatively, the notifier could describe the development of the production microorganism in sufficient detail to address any safety issues associated with use of that production microorganism. For enzyme preparations that would be used in human food, we recommend that notifiers consult our guidance entitled "Guidance for Industry: Enzyme Preparations: Recommendations for Submission of Chemical and Technological Data for Food Additive Petitions and GRAS Notices" (Ref. 33), and "Food-Processing Enzymes From Recombinant Microorganisms—A Review" (Ref. 43), for details about our recommendations for safety information regarding enzyme preparations derived from bioengineered microorganisms.

2. Potential Toxicants in the Source of the Notified Substance

(Comment 64) One comment agrees that a review of known toxicants that could be produced by the biological source of a notified substance should be part of the safety review, but recommends that the depth of the review be addressed on a case-by-case basis and be tailored to the substance and the source of the substance. This comment asserts that it would be difficult and impractical to define a method for this review or to define the specific toxicants that are required to be reviewed for each particular substance.

(Response 64) We agree that the safety review should be tailored to the substance and its source because of the diversity of toxicants that could be in the biological source. It is your responsibility to determine how to conduct the safety review; the rule does not prescribe any method for this review or any specific toxicants that must be reviewed for a particular substance or source. In some cases (*e.g.,* when it is well established in the scientific community that a source is non-toxigenic), citations to publicly available information about a biological source may be sufficient to address the safety of the notified substance with respect to potential toxicants in the source. In other cases (*e.g.,* when a source is known to be toxigenic), the information about the toxigenic source would lead you to a discussion, in the narrative required in Part 6 of a GRAS notice, of how the method of manufacture and specifications for the notified substance lead you to conclude that the notified substance as manufactured is safe and that the criteria for general recognition are satisfied.

(Comment 65) One comment refers to a statement we made, in the 2010 notice, that we have found that information about substances known to be toxicants is relevant regardless of the state of the science regarding the specific toxicity of the substance to humans (75 FR 81536 at 81540). This comment asserts that specifying that the identity of the notified substance include any known toxicants that could be in the source does not fully address whether the toxicants cause a safety concern. Another comment states that the "GRAS process" should contain a safety/risk assessment for known toxicants, not just identify the toxicants.

(Response 65) We agree that a GRAS notice must address the safety concerns associated with toxicants known to be in a biological source, not just identify the toxicants. See the requirements for a GRAS notice to include the method of manufacture of the notified substance (§ 170.230(b)), specifications for food-grade material (§ 170.230(c)), and a narrative explaining why the data and information in a GRAS notice provide a basis for the notifier's view that the notified substance is safe under the conditions of its intended use (§ 170.250).

(Comment 66) One comment recommends using our guidance entitled "Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions" (Ref. 31) as a more "holistic" approach to addressing potential safety concerns regarding known toxicants in a biological source, because the guidance describes how to use the manufacturing process to control, reduce, or concentrate toxicant levels and explains the importance of establishing limits for any known natural toxicants in or on food additives derived from a natural source. The comment asserts that this guidance should apply to GRAS substances as well as food additives because general recognition of safety through scientific procedures requires the same quantity and quality of evidence as is required to establish a food additive regulation for the use of the substance, and therefore the information about the identity of the substance should be consistent with the requirements for food additives. This comment notes that section III.A of "Recommendations for Submission of Chemical and Technological Data for

Direct Food Additive Petitions" clearly outlines the information needed for "allowing the unequivocal identification and characterization of the food additive" and that the principles in specific sections in section III.A of the guidance apply to GRAS substances even though they are written to specifically address food additives.

(Response 66) We agree that many of the recommendations in our guidance entitled "Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions" (Ref. 31) could be useful to a person who assesses whether a substance is GRAS under the conditions of its intended use. As the comment points out, the guidance currently is structured to address the specific requirements in § 171.1 (particularly § 171.1(c)) for food additive petitions. Consistent with available resources, we will consider revising that guidance to clarify how its recommendations apply to an evaluation of whether a substance is GRAS under the conditions of its intended use.

3. Particle Size

In the 2010 notice, we noted that substances that have a small particle size often have chemical, physical, or biological properties that are different from those of their larger counterparts (75 FR 81536 at 81540). We requested comment on whether the final rule should address, as part of identity, particle size and other chemical and physical properties that may be used to characterize engineered materials (see table 9).

(Comment 67) Some comments recommend that a GRAS notice discuss particle size only if it is relevant to the safety or effectiveness of the notified substance. One comment recommends that the rule not address particle size, at least until this area is better understood. Another comment asks us to clarify what we mean by the term "small particle size" if we include that term in the rule.

One comment asks us to require information about particle size and other physical/chemical properties that may be used to characterize engineered materials. This comment asserts that nanoparticles are not simply smaller versions of materials; instead nanoparticles are specifically engineered to create new properties and behaviors that give products certain attributes and highly reactive nanoparticles can exhibit a toxic reaction with their environments, including the cells of living organisms. This comment also notes that the U.S. Environmental Protection Agency (EPA) has already made case-by-case rulings on the safety of certain nanoparticles.

Several comments assert that any requirement for a GRAS notice to address particle size and other chemical or physical properties should apply only to engineered nanomaterials, and that it is not typically necessary to address such properties for non-engineered materials. One comment asserts that engineered nanomaterials could never be eligible for classification as GRAS because they either are new materials with unfamiliar properties or represent a significant new use of a material.

(Response 67) The final rule requires that a GRAS notice include scientific information that identifies the notified substance, and includes "characteristic properties" in a list of examples of appropriate information that a notifier would include. We agree that data and information about particle size, and any chemical and physical properties attributable to small particle size, are appropriate for engineered nanomaterials; a GRAS notice about an engineered nanomaterial likely would not provide an adequate basis for a conclusion of GRAS status without such information. We also agree that data and information about particle size may not be relevant for non-engineered materials and, thus, we are including the broad example of "characteristic properties" in the final rule without adding the narrow example of "particle size" (see § 170.230(a)(1)).

We note that we have several guidances applicable to significant manufacturing changes in food, including nanotechnology (Ref. 6; Ref. 8; and Ref. 44). Our guidance entitled "Guidance for Industry: Assessing the Effects of Significant Manufacturing Process Changes, Including Emerging Technologies, on the Safety and Regulatory Status of Food Ingredients and Food Contact Substances, Including Food Ingredients that are Color Additives" (Ref. 6) states: "At present, for nanotechnology applications in food substances, there are questions related to the technical evidence of safety as well as the general recognition of that safety, that are likely to be sufficient to warrant formal premarket review and approval by FDA, rather than to satisfy criteria for GRAS status." However, that guidance reflects the generally available data and information at present, and we disagree that data and information supporting the safety of engineered nanomaterials could never satisfy GRAS criteria. Whether the generally available data and information supporting the safety of the intended conditions of use of any substance—including an engineered nanomaterial—satisfy GRAS criteria is a case-by-case conclusion that depends on whether the generally available data and information support a conclusion that the substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use. Section 201(s) of the FD&C Act does not limit the eligibility of a substance for classification as GRAS based on factors such as its characteristic properties.

4. Other Comments About the Identity of the Notified Substance

(Comment 68) One comment asserts that the criteria used to conclude that a particular substance is GRAS, including details regarding biological source, known toxicants, particle size, etc., should be based on what qualified experts determine to be necessary.

(Response 68) We disagree that the role of qualified experts in a conclusion of GRAS status means that the requirements for a GRAS notice should be silent on the types of data and information that generally apply to any conclusion of GRAS status—in this case, data and information regarding the identity of the substance. In the narrative required by part 6 of a GRAS notice, a notifier must explain why the data and information in the notice provide a basis for the notifier's view that the notified substance is safe under the conditions of its intended use (§ 170.250(a)(1)); identify what specific data and information that the notifier discusses to support his view that the notified substance is safe under the conditions of its intended use are generally available, and what specific data and information that the notifier discusses are not generally available (§ 170.250(a)(2)); and explain how the generally available data and information that a notifier relies on to establish safety provide a basis for the notifier's conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use (§ 170.250(b)). The narrative is the appropriate mechanism for a notifier to explain how the view of qualified experts supports his view that the notified substance is GRAS under the conditions of its intended use.

B. Method of Manufacture

(Comment 69) Several comments address Issue 9a, *i.e.,* whether the final rule should continue to stipulate that the method of manufacture exclude any trade secrets, as proposed. Some of these comments support stipulating that the method of manufacture exclude any trade secrets. The stated reasons varied.

For example, some comments state that in the past experience of notifiers, it is generally possible to include sufficient information on the manufacturing process without disclosing trade secrets. One comment states that transparency, by both FDA and industry, and the use of publicly available information is critical to the continued success of the GRAS notification procedure. One comment states that the common knowledge element of the GRAS standard inherently limits the submission of confidential information and/or trade secrets by the notifier to substantiate a conclusion of GRAS status.

Other comments point to the proposed requirement that a GRAS notice include "detailed information about the . . . method of manufacture (excluding any trade secrets . . .)" and question whether a method of manufacture that excludes trade secrets can be sufficiently detailed to meet the requirements of a GRAS notice. One comment recommends that we clarify the rule by requiring that the notice include appropriate information on the method of manufacture, sufficient to conduct an adequate safety review, so that confidential information would not be submitted when a very general and non-confidential description suffices.

Several comments acknowledge that there may be situations where trade secret information is necessary to complete the description of the method of manufacture and recommend that the final rule provide flexibility for a notifier to provide trade secret information when appropriate (*e.g.,* to help us evaluate the GRAS notice), and for FDA to protect trade secrets or other confidential information in a GRAS notice from public disclosure, just as we would in the case of submissions such as food additive petitions. To promote clarity and transparency, some of these comments recommend revising the rule to require that a notifier who includes trade secret information explain why the information is trade secret and why the trade secret information has a corroborative role in the safety assessment. Some comments emphasize that a notifier who submits trade secret information must mark the information as non-public. Other comments assert that information identified as trade secret or confidential information should only be allowed if the information is not critical to a conclusion of GRAS status.

One comment suggests that a notifier could provide trade secret information to a GRAS panel for review on a confidential basis because deliberations of the panel would not necessarily be subject to public disclosure. One comment notes that supporting information can be valuable to a GRAS panel and allowing submission of confidential information in a GRAS notice could inform FDA of the full range of information taken into consideration by a GRAS panel.

Some comments cite our regulations for new drugs, premarket notification for medical devices, and premarket approval of medical devices as evidence that our regulations implementing FOIA specifically regard methods of manufacture as confidential and urge us to adopt a similar approach for GRAS notices.

See also Comment 57.

(Response 69) See table 11, and the regulatory text in §§ 170.230(b), 170.225(c)(8), 170.250(d), and 170.250(e), for a series of changes we made to the rule to address these comments about the method of manufacture included in a GRAS notice, including comments about trade secret information associated with the method of manufacture. Although the changes in Parts 1 and 6 of a GRAS notice broadly apply to any non-public information, in this response we focus on how these provisions apply to trade secret information that you may include in the description of the method of manufacture. Collectively, these changes: (1) Emphasize that the description of the method of manufacture must be in sufficient detail to evaluate the safety of the notified substance as manufactured, without stipulating that the method of manufacture exclude any trade secrets (§ 170.230(b)); (2) require the notifier to include a signed statement with his view as to whether the method of manufacture includes trade secret information (§ 170.225(c)(8)); (3) require the notifier to identify any trade secret information in the method of manufacture (§ 170.250(d)); and (4) require the notifier to explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to trade secret information that the notifier considered in concluding that the substance is safe under the conditions of its intended use (§ 170.250(e)). See also Response 57, Response 78, and section XVII.

TABLE 11—REQUIREMENTS THAT APPLY WHEN A NOTIFIER INCLUDES TRADE SECRET OR OTHER NON-PUBLIC INFORMATION IN A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Description	Revision
170.230(b)	170.36(c)(2)	In Part 2 of your GRAS notice, you must include a description of the method of manufacture in sufficient detail to evaluate the safety of the notified substance as manufactured.	• We replaced "detailed" with "sufficient detail to evaluate the safety of the notified substance as manufactured". • We no longer stipulate that the description of the method of manufacture must exclude trade secret information.
170.225(c)(8)	N/A	In Part 1 of your GRAS notice, you must state your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the FOIA (*e.g.,* as trade secret or as commercial or financial information that is privileged or confidential).	Requires a notifier who includes information that the notifier views as non-public information to make FDA aware of that view. See Response 57.
170.250(d)	N/A	In Part 6 of your GRAS notice (the narrative), if you view any of the data and information in your notice as exempt from disclosure under the FOIA, you must identify the specific data and information.	Requires a notifier who includes information that the notifier views as non-public information to identify the non-public information. See section XVII.

TABLE 11—REQUIREMENTS THAT APPLY WHEN A NOTIFIER INCLUDES TRADE SECRET OR OTHER NON-PUBLIC INFORMATION IN A GRAS NOTICE—Continued

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Description	Revision
170.250(e)		In Part 6 of your GRAS notice (the narrative), you must explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety-related data and information.	Requires a notifier to place non-public information in the context of a conclusion of GRAS status. See section XVII.
170.275(c)	170.36(f)(1)	We will disclose all remaining data and information that are not exempt from public disclosure in accordance with part 20.	Uses active voice to emphasize that we will apply the protections from public disclosure under the FOIA to non-public information included in a GRAS notice.

This rule establishes requirements for the information that a notifier submits to FDA in a GRAS notice. GRAS criteria require that any conclusion of GRAS status be based on common knowledge (see § 170.30(a)) and, thus, there could be no basis for a conclusion of GRAS status if trade secret information (or other non-public information) is necessary for qualified experts to reach a conclusion that the notified substance is safe under the conditions of its intended use. In the particular case of a conclusion of GRAS status through scientific procedures, GRAS criteria require that the conclusion of GRAS status be based on data, information, and methods that are generally available (see § 170.30(b)). Non-public information may be used to corroborate safety but cannot be used to establish safety; as discussed in Response 9, qualified experts must be able to conclude that the substance is not harmful under the conditions of its intended use without access to "corroborative" information (see § 170.30(a)).

We believe that it will be rare for a GRAS notice to include trade secret information. Likewise, we expect it will be rare that trade secret information would warrant sharing with members of a GRAS panel, because a notifier must write a non-confidential description of the method of manufacture to include in the GRAS notice and could share this non-confidential description, rather than trade secret information, with the GRAS panel. If the GRAS panel had questions about that description of the method of manufacture, we expect that the notifier would revise the description to address those questions rather than provide the GRAS panel with trade secret information to address those questions. If, however, a notifier does provide the GRAS panel with trade secret information, we agree that the notifier should inform us of the full range of information taken into consideration by the GRAS panel, consistent with the signed statement that the GRAS notice is a complete, representative, and balanced submission (see Response 58 and § 170.225(c)(9)). The notifier could do so either by including in his GRAS notice a non-confidential description of the trade secret information that was shared, or by providing the trade secret information shared with a GRAS panel. Importantly, the notifier would be required to explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public, safety related data and information (see Response 78 and § 170.250(e)). If the public description of the method of manufacture that a notifier includes in a GRAS notice cannot provide sufficient detail to evaluate the safety of the notified substance as manufactured, there could be no basis to support a conclusion of GRAS status. However, if that public description meets the requirements of the rule to provide sufficient detail to evaluate the safety of the notified substance as manufactured (see § 170.230(b)), it may be possible to explain that trade secret information that a GRAS panel evaluated is corroborative of safety rather than necessary to demonstrate safety.

Under § 20.61, trade secrets and commercial or financial information which is privileged or confidential are exempt from public disclosure. Under §§ 20.100(c)(7) and 171.1(h)(2)(i), manufacturing methods or processes, including quality control procedures, are exempt from public disclosure unless they have been previously disclosed to the public (as defined in § 20.81) or they relate to a product or ingredient that has been abandoned. If a notifier believes that all information about the method of manufacture should be non-public, it is unlikely that the notifier has a basis to conclude that the notified substance is GRAS under the conditions of its intended use. The use of the substance would be a food additive use and, if the notifier submits a food additive petition for that use, our regulations governing a food additive petition would protect the information from public disclosure, as do our regulations for new drugs, premarket notification for medical devices, and premarket approval of medical devices.

(Comment 70) Several comments express concern about the possibility that we would determine that information a notifier identifies as a trade secret or as confidential commercial information is available for public disclosure. One comment asserts that if we choose to allow the submission of confidential information in a GRAS notice, we should not be the party who determines whether information should be publicly disclosed. Another comment asks us to provide an opportunity for a notifier to make a "cease to evaluate" request before we disclose confidential information.

One comment asks us to allow the submission of limited confidential information to supplement (or corroborate) the publicly available information in a GRAS notice, such as by providing sufficient information in a GRAS notice to support a conclusion of GRAS status but also including additional, corroborating information in a food master file. The comment explains that the public GRAS notice would be complete and sufficient to form a conclusion of GRAS status, but we would have access to additional, confidential information that would ensure that we are informed of new manufacturing or technological developments. This comment points out that we have for many years employed food, drug, and medical device master files for the submission of confidential information.

(Response 70) We disagree that we should not be the party who determines whether information should be publicly disclosed. Under our public information regulations in part 20, we have the responsibility to determine whether information should be publicly disclosed, regardless of whether a person who submits the information has marked it as non-public. Marking records submitted to us as confidential, or with any other similar term, raises no obligation by FDA to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed (see § 20.27). We also disagree that providing an opportunity for a notifier to ask us to cease to evaluate a GRAS notice would impact the public disclosure of data and information that do not satisfy the criteria in part 20 for exemption from disclosure; under § 20.29 a GRAS notice is available for public disclosure in accordance with part 20.

Data and information submitted to us are available for public disclosure based on the nature of the data and information, not the name of the file where we store the data and information. Thus, asking us to store data and information that you view as confidential in a specific type of file, such as a "food master file," would not automatically protect the information from public disclosure. Furthermore, in Part 6 of your GRAS notice you would be required to explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to the confidential data and information in the separate file. We also would expect that you provide a statement in Part 1 of your GRAS notice with your view that the additional data and information in the separate file are exempt from disclosure under the FOIA (see § 170.225(c)(8)). Because part 20 already provides protection of non-public information from disclosure, and because your GRAS notice would need to both acknowledge the data and information in the separate file and explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to these data and information, we consider it administratively inefficient to maintain the data and information submitted in support of a conclusion of GRAS status in two separate files, and we may decide to decline to file a GRAS notice that is accompanied by a separate file containing data and information that you view as non-public.

(Comment 71) Some comments assert that many manufacturers will choose not to notify us of a conclusion of GRAS status because they expect that we will determine that all information submitted in a GRAS notice is available for public disclosure in most circumstances.

(Response 71) Our experience during the Interim Pilot program does not support the assertions in these comments. As noted in Response 24 and Response 26, CFSAN has filed more than 600 GRAS notices between 1998 and 2015, for an average of approximately 34 GRAS notices per year.

(Comment 72) One comment states that commercial and financial information are not relevant to the determination of safety of a notified substance.

(Response 72) Confidential commercial information may on occasion be used to corroborate safety. One example is an article that has been accepted for publication, but has not yet been published. This article would likely be considered confidential until it is published, but it could be used to corroborate other published information.

C. Specifications for the Notified Substance

We received no comments that disagreed with our proposed requirement for a GRAS notice to include specifications for food-grade material and we are finalizing it as proposed for a substance used in human food. See table 29 for an editorial change we made to the regulatory text for specifications for a substance used in animal food.

D. Data and Information Bearing on the Physical or Other Technical Effect of the Notified Substance

As discussed in section XXV.E, several comments discuss their experience with CVM's practice, during the Interim Pilot program, of asking a notifier to provide data or information demonstrating the effectiveness, or utility, of the notified substance. After considering these comments, we have added a requirement for Part 2 of a GRAS notice to include relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect, when necessary to demonstrate safety (see § 170.230(d) and Response 144). Data and information bearing on the physical or other technical effect the notified substance is intended to produce are only necessary when they bear on safety. This relationship to safety is consistent with the requirements of the FD&C Act for a petition to establish the safety of a food additive (see section 409(b)(2)(C) of the FD&C Act). An example of when such data and information would be relevant to safety is when the intended use of the notified substance is as an antimicrobial agent. For example, an antimicrobial agent may change the microbiological profile of food such that it suppresses one group of pathogenic microorganisms while allowing others to proliferate, thereby creating a potential health problem (Ref. 32).

XIV. Comments on Part 3 of a GRAS Notice: Dietary Exposure

We proposed that a notice regarding a conclusion of GRAS status through scientific procedures include a comprehensive discussion of, and citations to, generally available and accepted scientific data, information, methods, or principles that the notifier relies on to establish safety, including a consideration of the probable consumption of the substance and the probable consumption of any substance formed in or on food because of its use and the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances in such diet (proposed § 170.36(c)(4)(i)(A)). In the 2010 notice, we requested comment on several issues relevant to the proposed requirements for a comprehensive discussion that considers the probable consumption of the substance and the probable consumption of any substance formed in or on food because of its use and the cumulative effect of the substance in the diet, and noted that the simple term "dietary exposure" could be used in place of the statutory language (*i.e.*, derived from section 409(c)(5) of the FD&C Act) we used in the proposed rule (see table 12). See table 27 for issues in the 2010 notice regarding dietary exposure when a notified substance would be added to animal food.

TABLE 12—ISSUES IN THE 2010 NOTICE REGARDING DIETARY EXPOSURE WHEN A NOTIFIED SUBSTANCE WOULD BE ADDED TO HUMAN FOOD

Issue No.	Description of our request for comment	Reference
11a	Whether the final rule should continue to restate the statutory language of section 409(c)(5) of the FD&C Act or whether this provision should be stated more clearly, for example, by requiring information about dietary exposure (*i.e.*, the amount of the notified substance that consumers are likely to eat or drink as part of a total diet).	75 FR 81536 at 81540–81541.
11b	Whether a GRAS notice should be required to include information about dietary exposure to contemporary consumers regardless of whether the determination of GRAS status is through scientific procedures or through experience based on common use in food.	75 FR 81536 at 81540–81541.

In the following sections, we discuss comments on the proposed requirements applicable to dietary exposure and the issues discussed in the 2010 notice. After considering these comments, we are establishing requirements for Part 3 of a GRAS notice as shown in table 13, with editorial, clarifying, and conforming changes as shown in table 29. (See § 170.235). Table 13 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of some of the regulatory text of proposed § 170.36(c)(4)(i)(A) as § 170.235.

TABLE 13—FINAL REQUIREMENTS FOR DATA AND INFORMATION ABOUT DIETARY EXPOSURE IN PART 3 OF A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.235	170.36(c)(4)(i)(A) ...	11a 11b	In Part 3 of your GRAS Notice, you must provide data and information about dietary exposure (*i.e.*, the amount of relevant substances that consumers are likely to eat or drink as part of a total diet), regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food.	• Uses the term "dietary exposure" and describes it as meaning "the amount of relevant substances that consumers are likely to eat or drink as part of a total diet." • Requires data and information about dietary exposure regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food.
170.235(a)	170.36(c)(4)(i)(A) ...	11a	In Part 3 of your GRAS Notice, you must provide data and information about dietary exposure to the notified substance that includes exposure from its intended use and all sources in the diet.	Uses the term "dietary exposure."
170.235(b)	170.36(c)(4)(i)(A) ...	11a	When applicable, in Part 3 of your GRAS Notice you must provide data and information about dietary exposure to any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.*, hydrolytic products or reaction products).	• Uses the term "dietary exposure." • Gives examples of substances that could be formed in or on food because of the use of the notified substance.
170.235(c)	170.36(c)(4)(i)(A), 170.36(c)(2).	11a	When applicable, in Part 3 of your GRAS Notice you must provide data and information about dietary exposure to any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.*, contaminants or by-products).	Requires an estimate of dietary exposure to substances such as contaminants and by-products as a means to establish specifications for applicable contaminants and by-products.
170.235(d)	170.36(c)(4)(i)(A) ...	11a	In Part 3 of your GRAS notice, you must describe the source of any food consumption data that you use to estimate dietary exposure.	Specifies a necessary aspect of the proposed "comprehensive discussion" of scientific data, information, and methods.
170.235(e)	170.36(c)(4)(i)(A) ...	11a	In Part 3 of your GRAS notice, you must explain any assumptions you made to estimate dietary exposure.	Specifies a necessary aspect of the proposed "comprehensive discussion" of scientific data, information, and methods.

TABLE 13—FINAL REQUIREMENTS FOR DATA AND INFORMATION ABOUT DIETARY EXPOSURE IN PART 3 OF A GRAS NOTICE—Continued

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.250(a)(1)	170.36(c)(4)(i)(A) ...	N/A	In Part 6 of your GRAS notice, you must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet.	N/A.

See section XXV.F for a discussion of comments on the issues listed in table 27 regarding dietary exposure when a notified substance would be added to animal food and for changes we made to the regulatory text regarding dietary exposure when a notified substance would be added to animal food.

(Comment 73) Some comments support retaining the statutory language derived from section 409(c)(5) of the FD&C Act when stating the requirement for a comprehensive discussion in a GRAS notice that considers dietary exposure. One of these comments states that the proposed statutory language regarding dietary exposure is consistent with the criteria for general recognition of safety through scientific procedures, which requires the same quantity and quality of scientific evidence necessary for a food additive petition. Other comments support revising the proposed requirement as a means of clarifying that the comprehensive discussion in a GRAS notice must consider dietary exposure.

(Response 73) We agree that: (1) The requirements of the rule regarding what a notifier must include in a GRAS notice regarding dietary exposure must be clear; and (2) the statutory language of section 409(c)(5)(A) of the FD&C Act is consistent with the criteria for general recognition of safety through scientific procedures, which requires the same quantity and quality of scientific evidence necessary for a food additive petition. To meet both of these goals, the final rule requires information about dietary exposure (*i.e.*, the amount of relevant substances that consumers are likely to eat or drink as part of a total diet), as we suggested in the 2010 notice, but also retains the detailed statutory direction as proposed (see § 170.235(a) through (c), § 170.250(a)(1), and table 13). In addition to requiring an estimate of dietary exposure to the notified substance (§ 170.235(a)), the rule requires, when applicable, that a notifier provide data and information about dietary exposure to any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.*, hydrolytic products or reaction products) (§ 170.235(b)). Example of such substances are benzoates (which react with ascorbic acid (such as in beverages) to form benzene) and sulfur dioxide (which reacts irreversibly with thiamine, such that we have prescribed limitations on the use of sulfur dioxide in some food products (see § 182.3862)). The rule also requires, when applicable, that a notifier provide data and information about dietary exposure to any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.*, contaminants or by-products). An estimate of dietary exposure to substances such as contaminants and by-products is necessary to establish specifications for applicable contaminants and by-products (see § 170.230(c), which requires that a GRAS notice include specifications for food-grade material). See also Response 75.

(Comment 74) One comment asks us to allow for a reasonable methodology that does not overestimate dietary exposure in the extreme.

(Response 74) The rule neither prescribes the methodology you would use to estimate dietary exposure nor requires that you overestimate dietary exposure. Consistent with the proposed requirement for the consideration of dietary exposure to be a "comprehensive discussion," the rule requires you to describe the source of any food consumption data that you use to estimate dietary exposure and any assumptions you made to estimate dietary exposure; such information is necessary for the estimates of dietary exposure to be scientifically sound and provides an opportunity for you to explain why the methodology you used is reasonable (see § 170.235(d) and (e) and table 13). Our guidance entitled "Estimating Dietary Intake of Substances in Food" provides general recommendations for calculating and submitting estimates of dietary intake to support the documentation of the safety of substances introduced into food either intentionally to accomplish a technical effect, adventitiously as a component of an added substance, or inadvertently through contamination resulting from processing (Ref. 25).

(Comment 75) One comment emphasizes that the requirement for consideration of dietary exposure must discuss the potential cumulative effect of the notified substance.

(Response 75) We agree. We are specifying that the narrative included in Part 6 of a GRAS notice must address the safety of the notified substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet (see § 170.250(a)(1)).

(Comment 76) Some comments support requiring that a GRAS notice include information about dietary exposure to contemporary consumers when the conclusion of GRAS status is through experience based on common use in food prior to 1958, *e.g.*, because dietary exposure to contemporary consumers serves as a baseline for future studies/assessment. Other comments do not support such a requirement and assert that it is not critical to update the exposure data if consumption of the GRAS substance was already widespread before 1958, or that information about dietary exposure to contemporary consumers would only be necessary if the exposure has significantly changed since 1958.

One comment questions the value of requiring information about contemporary dietary intake of an ingredient that is GRAS through experience based on common use in foods. This comment asserts that the

FD&C Act deems an ingredient to be GRAS if it was commonly used in foods prior to January 1, 1958, and that FDA has long recognized that a conclusion of GRAS status through experience based on common use in food may be made without the quantity or quality of scientific procedures required for establishment of a food additive regulation. This comment asserts that there is no requirement for a GRAS ingredient to be consumed at the same use level as in 1958 and that imposition of such a new requirement may be impracticable, *e.g.,* because there may not be any databases that would allow for the calculation of dietary exposures prior to 1958. This comment also asserts that in many instances there may be insufficient information to establish an acceptable daily intake (ADI) for the ingredient because studies that can be used to calculate ADIs may not be available for many of these ingredients, and that without information about the ADI it would be difficult to imagine the relevance of the estimated daily intake, which would be calculated through dietary exposure.

Another comment asserts that §§ 170.30(c) and 170.3(f) clearly provide that for a substance to be GRAS through experience based on common use in food there must be a substantial history of consumption of the substance in food by a significant number of people prior to 1958 and that the requirements for information about consumption data in a GRAS notice should be consistent with those regulatory provisions. This comment also asserts that requiring information about dietary exposure to contemporary consumers would represent an additional regulatory burden that would not impact the original conclusion of GRAS status through experience based on common use in food if there are no safety concerns when the notified substance is used in accordance with the intended conditions of use.

(Response 76) We are requiring that a notifier provide data and information about dietary exposure, regardless of whether the conclusion of GRAS status is through scientific procedures or through experience based on common use in food (see § 170.235). The FD&C Act and our regulations do not provide that a substance is necessarily GRAS under the conditions of its intended use merely because it was commonly used in food prior to 1958. Rather, the FD&C Act provides that such a substance must be generally recognized, among experts qualified by scientific training and experience to evaluate its safety, through experience based on common use in food, to be safe under the conditions of its intended use. Under both the FD&C Act and the definition of "safe" in our regulations, relevant factors must be considered, including the "probable consumption of the substance and of any substance formed in or on food because of its use" (see section 409(c)(5)(A) of the FD&C Act and § 170.3(i)(1)). We recognize that a conclusion of GRAS status through experience based on common use in food does not require the same quantity or quality of scientific information required for establishment of a food additive regulation; however, this means that a conclusion of GRAS status through experience based on common use in food is not necessarily supported by the same testing data as would be required to support establishment of a food additive regulation. See, for example, the 1976 final rule establishing GRAS criteria, which provides, "for those substances that were widely used before 1958, under the terms of the statute FDA must consider available data and may not prohibit use of a substance merely because tests that would be required for new food additives have not been performed." (41 FR 53600, December 7, 1976). Like a conclusion of GRAS status based on scientific procedures, a conclusion of GRAS status through experience based on common use in food requires that the substance be "safe," as defined in 21 CFR 170.3(i), under the conditions of its intended use.

The rule requires that a notifier provide evidence of substantial history of consumption of the substance for food use by a significant number of consumers prior to January 1, 1958, but does not require an estimate of dietary exposure prior to 1958 (see § 170.245). The rule requires that the narrative in Part 6 of a GRAS notice explain why the data and information in the notice provide a basis for the notifier's view that the notified substance is safe under the conditions of its intended use, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet (§ 170.250(a)); to do so, the notifier must consider the estimated dietary exposure (which this comment refers to as "estimated daily intake"). However, the rule does not specify that a notifier must determine an "acceptable daily intake" as part of the narrative.

XV. Comments on Part 4 of a GRAS Notice: Self-Limiting Levels of Use

We proposed that a GRAS notice must include information on any self-limiting levels of use (proposed § 170.36(c)(3)). We did not receive comments disagreeing with this proposed requirement. Therefore, we are establishing a requirement for you to include in Part 4 of your GRAS notice data and information on self-limiting levels of use in circumstances where the amount of the notified substance that can be added to food is limited because food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical (see § 170.240). We included an explanation of the circumstances in which the level of use is self-limiting for clarity.

XVI. Comments on Part 5 of a GRAS Notice: Common Use in Food Before 1958

We proposed that a GRAS notice include a comprehensive discussion of, and citations to, generally available data and information that the notifier relies on to establish safety, including evidence of a substantial history of consumption of the substance by a significant number of consumers, for a conclusion of GRAS status through experience based on common use in food (proposed § 170.36(c)(4)(ii)(A)). During the Interim Pilot program, we received fewer than a dozen GRAS notices where the statutory basis was through experience based on common use in food (Ref. 45).

We did not receive comments disagreeing with this proposed requirement and we are establishing a requirement for you to include in Part 5 of your GRAS notice evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to January 1, 1958 if the statutory basis for your conclusion of GRAS status is through experience based on common use in food (see § 170.245). See table 29 for conforming changes for a substance used in animal food.

XVII. Comments on Parts 6 and 7 of a GRAS Notice: Narrative and List of Supporting Data and Information

We proposed that a GRAS notice must include a detailed summary of the basis for the notifier's determination that a particular use of the notified substance is exempt from the premarket approval requirements of the FD&C Act because such use is GRAS (proposed § 170.36(c)(4)). Regardless of whether the conclusion of GRAS status was based on scientific procedures or through experience based on common use in food, we proposed to require: (1) A comprehensive discussion of, and citations to, generally available and accepted scientific data and information that the notifier relies on to establish safety (proposed § 170.36(c)(4)(i)(A) and 170.36(c)(4)(ii)(A)); (2) a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with the GRAS determination (proposed § 170.36(c)(4)(i)(B) and (c)(4)(ii)(B)); and (3) the basis for concluding, in light of the data and information in the GRAS notice, that there is consensus among experts qualified by scientific training and experience to evaluate the safety of substances added to food that there is reasonable certainty that the substance is not harmful under the intended conditions of use (proposed § 170.36(c)(4)(i)(C) and (c)(4)(ii)(C)). When the conclusion of GRAS status is based on scientific procedures, we also proposed that the discussion of generally available and accepted information that the notifier relies on to establish safety include methods and principles, and include a consideration of the probable consumption of the substance and the probable consumption of any substance formed in or on food because of its use and the cumulative effect of the substance in the diet, taking into account any chemically or pharmacologically related substances in such diet (proposed § 170.36(c)(4)(i)(A)).

In the 2010 notice, we requested comment on issues relevant to the applicability of confidential data and information to a conclusion that a substance is GRAS under the conditions of its intended use (see table 14).

TABLE 14—ISSUES IN THE 2010 NOTICE REGARDING THE APPLICABILITY OF CONFIDENTIAL DATA AND INFORMATION TO A CONCLUSION OF GRAS STATUS

Issue No.	Description of our request for comment	Reference
9b	Whether to require that a notifier who identifies one or more trade secret(s), as defined in § 20.61(a), in the GRAS notice explain why it is trade secret information and how qualified experts could conclude that the intended use of the notified substance is safe without access to the trade secret(s).	75 FR 81536 at 81539–81540.
9c	Whether to require that a notifier who identifies confidential commercial or financial information, as defined in § 20.61(b), in the GRAS notice explain why it is confidential commercial or financial information and how qualified experts could conclude that the intended use of the notified substance is safe without access to such information.	75 FR 81536 at 81539–81540.

In the following paragraphs, we discuss comments on the proposed requirements applicable to a detailed summary of the basis for the notifier's conclusion of GRAS status and the issues discussed in the 2010 notice. After considering these comments, we are establishing requirements for Part 6 of a GRAS notice to include a narrative as shown in table 15, and for Part 7 of a GRAS notice to include a list of supporting data and information as shown in table 16, with editorial, clarifying, and conforming changes as shown in table 29. (See §§ 170.250 and 170.255.)

Table 15 and table 16 identify changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(c)(4) as §§ 170.250 and 170.255.

TABLE 15—FINAL REQUIREMENTS FOR A NARRATIVE IN PART 6 OF A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 6 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.250	170.36(c)(4)	N/A	You must include a narrative that provides the basis for your conclusion of GRAS status.	N/A.
170.250(a)(1)	170.36(c)(4)	N/A	You must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet.	N/A.
170.250(a)(2)	170.36(c)(4)	9a, 9b, and 9c	You must identify what specific data and information are generally available, and what specific data and information are not generally available, by providing citations to the list of data and information that you include in Part 7 of your GRAS notice.	Requires that your narrative clarify the status of all data and information that you rely on to establish safety.

TABLE 15—FINAL REQUIREMENTS FOR A NARRATIVE IN PART 6 OF A GRAS NOTICE—Continued

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 6 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.250(b)	170.36(c)(4)	N/A	You must explain how the generally available data and information that you rely on to establish safety provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use.	Uses the term "generally recognized" rather than the term "consensus."
170.250(c)	170.36(c)(4)	6b	You must either: (1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available; or (2) State that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status..	When applicable, requires an affirmative statement that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status.
170.250(d)	N/A	9b and 9c	In Part 6 of your GRAS notice (the narrative), if you view any of the data and information in your notice as exempt from disclosure under the FOIA, you must identify the specific data and information.	N/A.
170.250(e)	N/A	9b and 9c	In Part 6 of your GRAS notice (the narrative), you must explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access non-public, safety-related data and information.	Your explanation must address all non-public safety-related data and information, not just confidential data and information included in your GRAS notice.

TABLE 16—FINAL REQUIREMENTS FOR A LIST OF SUPPORTING DATA AND INFORMATION IN PART 7 OF A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description. Part 7 of your GRAS notice:	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.255(a)	• 170.36(c)(4)(i)(A) • 170.36(c)(4)(ii)(A)	9a, 9b, and 9c	You must include a list of all of the data and information that you discuss in part 6 of your GRAS notice to provide a basis for your view that the notified substance is safe under the conditions of its intended use.	Clarifies that the list includes all data and information, not just generally available data and information.
170.255(b)	• 170.36(c)(4)(i)(A) • 170.36(c)(4)(ii)(A)	9a, 9b, and 9c	The data and information that you list must specify which data and information are generally available, and which data and information are not generally available.	Requires that you characterize each item in your list as to whether it is generally available.

In the requirements for Parts 6 and 7 of the final rule, we made changes to require that the narrative in Part 6 of your GRAS notice, and the accompanying list of supporting data and information in Part 7 of your GRAS notice, clarify the status of all data and information that you rely on to establish safety as to whether it is generally available (see §§ 170.250(a)(2) and 170.255, table 15, and table 16). We made these changes relative to the proposed requirements for a detailed summary and comprehensive discussion for consistency with: (1) The criteria for eligibility for classification as GRAS through scientific procedures (which provide that a conclusion of GRAS status may be corroborated by the application of unpublished scientific data, information, or methods (see § 170.30(b), Response 8, and Response 12)); and (2) the provisions of the rule that allow you to include data and information that are not generally available (see § 170.230(b) (which no longer stipulates that the method of manufacture must exclude trade secret), § 170.225(c)(8), Response 57 and Response 69).

In the requirements for Part 6 of a GRAS notice, we also made a change to require that your narrative either: (1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available; or (2) state that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status. See § 170.250(c) and table 15. We made this change relative to the proposed requirement for a comprehensive discussion of any reports of investigations or other information that may appear to be inconsistent with a conclusion of GRAS status to emphasize your responsibility to seek out such reports and information, as we do during our evaluation of a GRAS notice. See also § 170.225(c)(9) and Response 58, in which we discuss the requirements for a statement certifying that the GRAS notice is "complete" in addition to "representative" and "balanced," to emphasize your responsibility to identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with a conclusion of GRAS status. Under §§ 170.225(c)(9) and 170.250(c), we expect you to describe unpublished reports of investigations or other information that may appear to be inconsistent with a conclusion of GRAS status, not just published reports. If we identify relevant information that was not discussed in the GRAS notice, we may question the credibility of the certification statements in the GRAS notice and respond with an "insufficient basis letter." As noted in Response 58, the use of certification statements has become routine in other submissions to FDA for food programs, and the certification statements in Form FDA 3480 (for a food contact notification submission) (Ref. 39) and in Form FDA 3537 (for registration of a food facility) (Ref. 40) remind the submitter of criminal penalties under 18 U.S.C. 1001 for a materially false, fictitious, or fraudulent statement to the U.S. Government. Now that certification statements will be required in a GRAS notice, we intend to modify the form that we make available for the submission of a GRAS notice (*i.e.,* Form FDA 3667 (Ref. 38)) to likewise remind any person who submits a GRAS notice of the applicability of criminal penalties for a materially false, fictitious, or fraudulent statement to the U.S. Government.

See also Response 78. We also expect you to describe unpublished data and information that you consider to be corroborative of safety (*e.g.,* if you consider that the unpublished data and information warrant sharing with any "GRAS panel" that you convene).

(Comment 77) One comment asserts that the proposed requirement for a GRAS notice to include the basis for concluding that there is consensus among qualified experts about the safety of the substance misstates the statutory standard for general recognition in section 201(s) of the FD&C Act. This comment asserts that the term "consensus" denotes complete or near unanimity, whereas the standard of general recognition requires that qualified experts predominantly, but not unanimously, accept the safety of the substance. Although the comment acknowledges that the proposed rule stated that the term "consensus" does not imply unanimity (62 FR 18938 at 18941), the comment argues that the example used in our explanation, about whether a single published report questioning the safety of use of a substance in food would preclude general recognition, wrongly implied that general recognition requires near unanimity (62 FR 18938 at 18941). The comment asks us to revise the rule by replacing the term "consensus," which does not appear in the statute, with the phrase "general recognition," which derives from the statute itself.

(Response 77) As discussed in the proposed rule (62 FR 18938 at 18939), our interpretation that general recognition requires consensus is consistent with the case law on the general recognition standard. See *United States* v. *Western Serum Co., Inc.,* 666 F.2d 335, 338 (9th Cir. 1982); *United States* v. *Articles of Drug...Promise Toothpaste,* 624 F.Supp. 776, 778 (N.D. Ill. 1985), aff'd 826 F.2d 564 (7th Cir. 1987); *United States* v. *Articles of Drug...Hormonin,* 498 F.Supp.2d 424, 435 (D.N.J. 1980). See also the discussion of the consensus standard in Response 20.

We proposed to provide our interpretation of section 201(s) of the FD&C Act in the requirement for Part 6 of a GRAS notice to provide more context to notifiers than merely repeating the statutory language. We disagree with the comment's assertion that the example we described in the proposed rule requires "near unanimity"; CFSAN's experience during the Interim Pilot program demonstrates that CFSAN's "insufficient basis letters" did not apply a standard of "near unanimity" when evaluating the notifier's basis for a conclusion of GRAS status (see section III.A.3 of CFSAN's 2010 experience document (Ref. 18)).

However, we have decided to use the statutory language (*i.e.,* "generally recognized") rather than the proposed term "consensus" because the revised GRAS criteria that we are establishing in § 170.30 continue to use the statutory language rather than the consensus standard applied by the courts in applying the statutory language to specific situations. Using the statutory language in both the GRAS criteria and the requirement for the submission of a narrative in a GRAS notice will emphasize your burden to explain how the data and information in the notice regarding the safety of the notified substance under the conditions of its intended use satisfy the GRAS criteria.

See also Response 128, in which we respond to comments recommending that we clarify that the same standards apply to a conclusion of GRAS status regardless of whether the conclusion is submitted to us as a GRAS notice or is not submitted to us. As noted in Response 128, we believe that the provisions of the GRAS notification procedure will be a useful resource to any person who intends to use a substance in food based on a conclusion of GRAS status, regardless of whether the conclusion of GRAS status is submitted to us in a GRAS notice. In developing any recommendations (*e.g.,* in guidance) that would broadly apply to any conclusion of GRAS status, it is simpler to consistently use the same regulatory text in both the GRAS criteria and the submission requirements for a GRAS notice.

(Comment 78) One comment notes that industry has various options for handling confidential information. For example, confidential agreements are commonly used instruments to help maintain the confidentiality of proprietary trade secret information, and therefore qualified experts on GRAS panels can have access to such information if it is necessary for a conclusion of GRAS status. The comment asks us to require that notifiers indicate whether qualified experts (such as on the notifier's GRAS panel) had access to trade secrets when they concluded that the substance is safe under the conditions of its intended use.

(Response 78) The rule establishes no requirements specific to a GRAS panel. However, we agree that it is appropriate for a notifier to indicate whether qualified experts (such as on the notifier's GRAS panel) who reviewed the data and information supporting safety had access to safety-related trade secrets in reaching a conclusion that the notified substance is safe under the conditions of its intended use. Therefore, we are requiring that a notifier explain how there could be a basis for a conclusion of GRAS status if qualified experts generally do not have access to non-public safety-related data and information (see § 170.250(e)). This requirement applies to all non-public safety-related data and information, not just trade secret information, and is not limited to non-public safety-related data and information that are included in the notice. As requested by the comment, this requirement would apply if the notifier provided non-public safety-related information to outside experts (such as on a GRAS panel). As already discussed, if a GRAS panel considers non-public safety-related information that a notifier does not include in a GRAS notice, we also expect the notifier to inform us that the GRAS panel had access to such information, consistent with the notifier's signed statement that the GRAS notice is a complete, representative, and balanced submission (see § 170.225(c)(9)) (see Response 58 and Response 69).

See also table 11 and table 15. The rule also requires that a notifier state his view as to whether any of the data and information in Parts 2 through 7 of a GRAS notice are exempt from disclosure under the FOIA (see § 170.225(c)(8)) and identify what specific data and information in the notice are generally available, and what specific data and information in the notice are not generally available (see § 170.250(a)(2) and (d)). Collectively, the requirements in §§ 170.225(c)(8) and (9) and 170.250(a)(2), (d), and (e) address the underlying issue in the comment's request, *i.e.*, that there must be a basis for a conclusion of GRAS status if some safety-related data and information that a notifier assesses in his deliberations are non-public (*e.g.*, trade secret information or otherwise are confidential information), regardless of whether the notifier shares such information with a GRAS panel. If a GRAS notice does not provide a basis for a conclusion that the notified substance is safe under the conditions of its intended use without access to such information, we would respond to the notice with an ''insufficient basis letter.'' If we respond with a ''no questions letter,'' and later determine that the GRAS notice was not ''complete'' (*e.g.*, because it did not describe unpublished reports of investigations that are, or may appear to be, inconsistent with the conclusion of GRAS status), we may send the notifier a subsequent letter regarding the omission; such a letter would be readily accessible to the public (§§ 170.265(c) and 170.275(b)(2)).

(Comment 79) One comment suggests that if the qualified experts are FDA reviewers, an option might be for the notifier to submit a ''sanitized'' version of the GRAS notice, excluding non-public information, together with a separate appendix to the GRAS notice where the notifier would include relevant trade secrets or confidential information needed to support the conclusion of GRAS status. Alternatively, we could require that a notifier submit two versions of the submission: (1) A sanitized version that excludes non-public information; and (2) a more detailed version including the confidential information. The comment states that these options would both allow our reviewers access to the information and facilitate the process of promptly making GRAS notices available for public disclosure.

(Response 79) In enacting the GRAS provision, Congress clearly contemplated a process of concluding that a food substance is GRAS under the conditions of its intended use as an alternative to submission of a food additive petition to FDA and establishment of a regulation prescribing the conditions under which the substance may be safely used. It follows that the qualified experts who evaluate the basis for a conclusion that the notified substance is safe under the conditions of its intended use must not exclusively be ''FDA's experts'' (such as our scientific staff who evaluate GRAS notices). The suggestion of this comment that a notifier could rely exclusively on evaluation by FDA experts to support his view that there is a basis for concluding that there is consensus among ''qualified experts'' is inconsistent with the GRAS provision in section 201(s) of the FD&C Act, which requires general recognition among qualified experts. See also the discussion in Response 70, in which we explain our reasons for why we may decide to decline to file a GRAS notice that is accompanied by a separate file containing data and information that you view as non-public.

XVIII. Comments on Steps a Notifier May Take Before We Respond to a GRAS Notice

In the 2010 notice, we described comments regarding steps you may take before we respond to your GRAS notice (see table 17). As noted in section VIII.A, we are establishing a definition for ''amendment'' in the rule (see § 170.203). In the following paragraphs, we discuss additional comments regarding the issues in table 17. Some of these comments agree that the rule should have such a provision. Other comments ask us to clarify how such a provision would operate in practice (see, *e.g.*, Comment 82) or suggest one or more changes to the provision as we described it in the 2010 notice (see, *e.g.*, Comment 80, Comment 81, and Comment 83). After considering these comments, we are establishing two provisions regarding steps you may take before we complete our evaluation of a GRAS notice. The first provision specifies that you may submit a timely amendment to your filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice by letter (see the regulatory text of § 170.260(a)). The second provision specifies that you may ask us to cease to evaluate your GRAS notice as described in the 2010 notice, with clarifications as a result of comments (see the regulatory text of § 170.260(b)). One clarification is that such a request does not preclude you from submitting a future GRAS notice with respect to the notified substance. A second clarification is that we will send you a letter informing you of our decision regarding your request (see the regulatory text of § 170.265(b)(3)).

TABLE 17—ISSUES IN THE 2010 NOTICE REGARDING STEPS YOU MAY TAKE BEFORE WE RESPOND TO YOUR GRAS NOTICE

Issue No.	Description of our request for comment	Reference
3a	Whether to define ''amendment'' to mean any data or other information that you submit regarding a filed GRAS notice before we respond to the notice.	75 FR 81536 at 81538.
5	Whether the final rule should explicitly provide that you may request in writing that we cease to evaluate your GRAS notice at any time during our evaluation of that GRAS notice.	75 FR 81536 at 81538–81539.

See section XXV.I for a discussion of comments regarding steps you may take before we respond to your GRAS notice for a substance used in animal food, and for our response to those comments.

A. Communicating With a Notifier Before We Respond to a GRAS Notice

(Comment 80) Several comments note that the proposed rule did not say that we would contact a notifier, before we issue our publicly available response, to provide preliminary feedback regarding our evaluation of a GRAS notice. One of these comments asks us to include a provision specifying that we may communicate with the notifier about any aspect of a notice while the notice is pending. Some comments express concern that a letter listing answerable and nonsubstantive questions about a GRAS notice could cause confusion and misunderstanding in the marketplace, particularly if additional information, clarification, or amendment would address our concerns.

(Response 80) We decline the request to include a provision specifying that we may communicate with you about any aspect of a notice while your notice is pending. As discussed in section III.C.1 of CFSAN's 2010 experience document (Ref. 18), during the Interim Pilot program CFSAN contacted several notifiers to request clarification about data and information in the notice under the framework of existing regulations governing meetings and correspondence (§ 10.65(g)). It is not necessary to duplicate the existing procedures in § 10.65(g) in the requirements for the GRAS notification procedure.

We infer that this comment is specifically asking us to require that we contact you to provide preliminary feedback before we respond to your GRAS notice with an "insufficient basis letter." As discussed in section III.C.1 of CFSAN's 2010 experience document (Ref. 18), our experience during the Interim Pilot program demonstrates that we are willing to engage in a dialog with a notifier to clarify particular aspects of a GRAS notice. As discussed in section IV.H.4 of CFSAN's 2010 experience document (Ref. 18), our experience during the Interim Pilot program also demonstrates that we do not issue an "insufficient basis letter" with "nonsubstantive questions." Although we have issued "insufficient basis letters" due to an overall poor quality of a submission, to conserve resources our practices have evolved so that we generally do not file such submissions as GRAS notices (see section XIX.A regarding filing decisions and section III.K of CFSAN's 2010 experience document (Ref. 18)). Although we expect to contact you when we have questions, whether we intend to provide you with an opportunity to submit an amendment to a GRAS notice before responding to the notice has been, and will continue to be, a matter committed to our discretion.

In the following paragraphs, we discuss some key factors we intend to consider regarding the purpose of our contact with you regarding your GRAS notice, particularly with respect to whether we intend to provide you with an opportunity to submit an amendment to a GRAS notice. These factors are: (1) Whether our questions can be addressed by a timely, clarifying amendment; (2) whether our evaluation identifies a safety concern; and (3) whether we question whether GRAS criteria are satisfied, even if our evaluation does not identify a safety concern. See also the discussion in Response 85 regarding factors that could lead us to decline to file a submission as a GRAS notice, rather than to file it for our evaluation of your view that the notified substance is GRAS under the conditions of its intended use and issue an "insufficient basis letter."

We agree that an "insufficient basis letter" listing answerable questions about a GRAS notice could cause confusion and misunderstanding in the marketplace, particularly if additional information, clarification, or amendment would address our concerns. Section III.C.1 of CFSAN's 2010 experience document provides examples of circumstances where CFSAN contacted a notifier and expected that the information exchanged between CFSAN and the notifier would clarify, rather than substantively amend, the original notice. We intend to continue contacting notifiers in such circumstances. By "clarify, rather than substantively amend," we mean that the amendment would add or modify specific sections in the notice, not that the clarifying information would necessarily be nonsubstantive in nature. For example, as discussed in Response 96 during the Interim Pilot program we contacted notifiers when the notice contained insufficient information about dietary exposure and when the notice contained insufficient information to adequately identify the substance. We did so because it is efficient, for us as well as the notifier, to bring a GRAS notice to closure with a "no questions letter" when it is likely that a timely, clarifying amendment would resolve our questions. For example, it is more efficient for us to bring a GRAS notice to closure while our reviewers are already immersed in the substantive evaluation of the notice, rather than to issue an "insufficient basis letter" and begin the evaluation process anew when the notifier addresses the questions in a new GRAS notice. See section XVIII.B for a discussion of what we mean by a "timely" amendment.

If we file your submission as a GRAS notice and our evaluation of the available data and information identifies a safety concern, the purpose of our contact with you would depend on whether the safety concern could be addressed by a timely, clarifying amendment. For example, in some cases the available data and information may support safety only under modified conditions of use relative to the conditions of use described in your GRAS notice, and our contact with you would focus on your opportunity to address the safety concern through a timely amendment specifying modified conditions of use. However, if we believe that the safety concern could not be addressed through a timely, clarifying amendment or by re-submission of a new GRAS notice (*e.g.,* after studies are conducted to address the safety concern), we likely would contact you to make you aware of our concerns and then issue an "insufficient basis letter" that clearly and fully articulates our reasons for that safety concern, including the full context of the risk to human or animal health.

If we file your submission as a GRAS notice and find that your narrative does not support a conclusion of GRAS status, even if the available data and information support your view that the notified substance is safe under the conditions of its intended use (*e.g.,* because data and information that are necessary to establish safety are not generally available), the purpose of our contact with you would focus on your opportunity to address the regulatory status of the notified substance. For example, it may be possible for you to submit a new GRAS notice after publishing applicable data and information and allowing sufficient time to allow the expert scientific community to access the published information. Alternatively, it may be more appropriate for you to consider the notified substance as a food additive under the conditions of its intended use, and to make a premarket submission such as a food additive petition. For examples of circumstances leading to the options for addressing questions about the regulatory status of the substance when we have not identified a safety concern, see section III.A.4 of CFSAN's 2010 experience document (Ref. 18). Any letter we issue would include our view of the regulatory status of the substance at the time that we issued the letter, based on the generally available data and information at that time.

B. Submitting an Amendment

Comments support adding a provision to clarify that you may submit an amendment to your GRAS notice and, thus, we are establishing a provision specifying that you may submit a timely amendment to your filed GRAS notice (§ 170.260(a)). In some cases, you would submit such an amendment after we contact you to discuss our questions about your GRAS notice. (See the discussion in Response 80 regarding contacting a notifier.) In other cases, you may conclude that it is appropriate to submit an amendment to update your GRAS notice on your own initiative, *e.g.*, if new data and information about the notified substance under the conditions of its intended use become available after we file your submission as a GRAS notice. Depending on the circumstances, you could then decide to explain your view that the new data and information do not alter the basis for your conclusion of GRAS status; alternatively, you could decide to ask us to cease to evaluate your GRAS notice while you evaluate the impact of the new data and information on the GRAS status of the notified substance under the conditions of its intended use (see § 170.260(b)).

By timely, we mean that you submit your amendment in a timeframe that provides us with sufficient time to evaluate it before we respond to your GRAS notice. Given that the rule requires us to end our evaluation and respond to your GRAS notice within 180 days, with an extension of up to an additional 90 days on an as needed basis § 170.265(b)(1)), we reserve the right to not consider your amendment if you submit it so late in our evaluation that it would impact our ability to respond within our established timeframes. Therefore, as a companion provision, the rule also provides that we will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter based on our evaluation of your notice if we deem that doing so is feasible within the established timeframes (see § 170.265(a)(4)). If we deem that considering your amendment is not feasible within the established timeframes, we will inform you that we are not considering your amendment.

See also the discussion in Response 101, which emphasizes that the role of an amendment is to clarify questions that we have about your conclusion of GRAS status rather than to substantively amend the GRAS notice.

C. Notifier's Request That We Cease To Evaluate a GRAS Notice

(Comment 81) Some comments ask us to make public the reason for a notifier's request that we cease to evaluate a notice. One comment asks that any new information, or questions about the scientific consensus about whether a substance is safe, be made clear to the public as well as FDA. Another comment expresses concern that companies ask FDA to cease evaluations of their GRAS notices with "alarming frequency."

(Response 81) We are establishing a provision specifying that a notifier may ask us to cease to evaluate his GRAS notice (see § 170.260(b)). As a companion provision, we are specifying that if a notifier asks us to cease to evaluate a GRAS notice, we will send the notifier a letter informing the notifier of our decision regarding that request (see § 170.265(b)(3)). As discussed in section III.E of CFSAN's 2010 experience document (Ref. 18), during the Interim Pilot program CFSAN's "cease to evaluate letters" generally repeated any reason specified in a request letter, but may not have otherwise described the reasons underlying the request. If a notified substance is marketed even though we issue a "cease to evaluate letter," there could be confusion about the GRAS status of the notified substance even when the conditions of use in the marketplace differ from the notified use that was the subject of the "cease to evaluate letter." For example, a notifier could ask us to cease to evaluate a GRAS notice because we identified a safety concern about the specified use level of the notified substance in food products, and then decide to market the substance at a lower use level than the level specified in the GRAS notice, where we would no longer have that concern. In addition, as discussed in the proposed rule we proposed to make all response letters readily accessible to the public because such a system will properly underscore a notifier's acceptance of responsibility for the conclusion of GRAS status, and a GRAS notice that is submitted to us is a public notice (62 FR 18938 at 18953). A "cease to evaluate letter" signals that a submitted GRAS notice does not provide an adequate basis for a conclusion that the notified substance is GRAS under the conditions of its intended use, even though we do not issue an "insufficient basis letter." Given the public nature of a GRAS notice, it is appropriate for the reasons leading to a "cease to evaluate letter" to also be public. Therefore, as of October 17, 2016, we intend to change this practice and increase transparency by describing the reasons leading to any "cease to evaluate letter."

Table 1 in CFSAN's 2010 experience document (Ref. 18) shows that approximately 16 percent of GRAS notices that CFSAN responded to during the 12-year period spanning 1998 through 2009 came to closure when the notifier asked us to cease to evaluate a GRAS notice. Table 1 in CFSAN's 2010 experience document also shows that CFSAN issued equal numbers of "cease to evaluate letters" and "insufficient basis letters" during the years 1998 through 2002 (*i.e.*, 16 "cease to evaluate letters" and 16 "insufficient basis letters"). However, during the years 2003 through 2009 CFSAN issued 31 "cease to evaluate letters," but no "insufficient basis letters." In addition, table 1 in CFSAN's 2016 experience document (Ref. 19) shows that during the years 2010 through 2015 CFSAN issued 48 "cease to evaluate letters" but only one "insufficient basis letter." We acknowledge that there has been a distinct shift between the ratio of the number of "cease to evaluate letters" compared to the number of "insufficient basis letters" issued during the years 1998 through 2002 and the corresponding ratio for letters issued during the years 2003 through 2015. We consider that the data in the experience document demonstrate an evolving practice in which CFSAN has declined to file some submissions as GRAS notices when the notice lacks much of the required data and information necessary for us to evaluate a notifier's view that the notified substance is GRAS under the conditions of its intended use (see Response 85). In addition, such a frequency demonstrates that CFSAN has been willing to contact notifiers with questions about a conclusion that the notified substance is GRAS under the conditions of its intended use. As discussed in Response 80, when our questions cannot be addressed by a timely amendment, contacting the notifier provides the notifier an opportunity to re-submit a new GRAS notice or other regulatory submission (such as a food additive petition) that addresses our questions.

As discussed in section III.E of CFSAN's 2010 experience document (Ref. 18), in many cases a notifier who received a "cease to evaluate letter" resubmitted a new GRAS notice, and CFSAN responded with a "no questions letter." For many GRAS notices, the questions we raised and discussed with the notifier clearly addressed issues other than a fundamental safety concern. For example, some of the letters that CFSAN lists in section III.E of its 2010 experience document provide reasons such as preparing a new notice that will not contain any confidential business information and that will clarify that the statutory basis for the conclusion of GRAS status is through scientific procedures; needing to revise an estimate of dietary exposure; and clarifying and providing additional information for a new notice. However, CFSAN only made these reasons transparent to the public because the notifier chose to provide these reasons in his request that we cease to evaluate the GRAS notice. In other circumstances, the public had no way to know what the issue was until we responded to the resubmitted notice. We intend to continue to contact a notifier to discuss our questions, and provide an opportunity for the notifier to ask us to cease to evaluate the GRAS notice (*e.g.,* so that the notifier can submit a new GRAS notice that addresses the issues). However, we also intend to briefly describe these issues in a ''cease to evaluate letter'' that follows that contact. As CFSAN did during the Interim Pilot program, we intend to consider any reasons a notifier provides for the request, and to include those reasons in our ''cease to evaluate letter.'' If, however, we conclude that a notifier's explanation does not adequately describe the reasons leading to a ''cease to evaluate'' request, we intend to explain the reasons for ceasing to evaluate the notice from our point of view. Doing so will both ensure clear communication about the reasons and make the reasons transparent to the public.

As discussed in Response 80, if we identify a safety concern and believe that the safety concern could not be addressed through a timely, clarifying amendment, by re-submitting a new GRAS notice, or by submitting another premarket submission (such as a food additive petition), we likely would issue an ''insufficient basis letter'' even though we would have contacted the notifier to discuss our concerns.

Asking us to cease to evaluate a GRAS notice does not guarantee that we will honor that request. Depending on the circumstances, we may decide to decline the request and instead respond with an ''insufficient basis letter''; depending on the time remaining between when we receive the request and the timeframes by which we must respond to the GRAS notice, we may either send the notifier a separate letter declining the request, or note in the ''insufficient basis letter'' that we had declined the request. See the discussion in section III.C.1 of CFSAN's 2010 experience document (Ref. 18) for an example of a situation in which CFSAN responded with an ''insufficient basis letter'' after a notifier asked CFSAN to cease to evaluate its GRAS notice, submitted a new GRAS notice, and asked CFSAN to cease to evaluate the second submitted GRAS notice.

(Comment 82) One comment asks us to clarify that a notifier's request that we cease to evaluate a GRAS notice would be without prejudice for future submissions.

(Response 82) The final provision specifies that your request that we cease to evaluate a GRAS notice does not preclude you from submitting a future GRAS notice with respect to the notified substance.

(Comment 83) One comment asks us to specify that, if feasible, the files could be returned to the notifier at the notifier's expense.

(Response 83) We decline this request. As discussed in the 2010 notice (75 FR 81536 at 81538–81539), our current regulations regarding public information stipulate that no person may withdraw records submitted to FDA (see § 20.29), and those regulations will apply to any GRAS notice that we receive. To make this clear, the provision we are establishing in the final rule provides an opportunity for you to ask us to ''cease to evaluate'' a GRAS notice rather than ''withdraw'' a GRAS notice.

(Comment 84) Some comments ask us to specify that if a notifier requests that we cease to evaluate a submitted GRAS notice, such notices will remain in our files and will be available for public disclosure.

(Response 84) See § 20.29 and the discussion of Issue 5 in the 2010 notice (75 FR 81536 at 81538–81539). If a notifier asks us to cease to evaluate a submitted GRAS notice, the notice will remain in our files and will be available for public disclosure in accordance with part 20. It is not necessary to repeat the provisions of § 20.29 in the GRAS notification procedure.

XIX. Comments on What We Will Do With a GRAS Notice

We proposed that: (1) We would acknowledge receipt of a notice, within 30 days of receipt, by informing the notifier in writing of the date on which the notice was received (proposed § 170.36(d)); (2) we would respond to the notifier in writing within 90 days of receipt of the notice (proposed § 170.36(e)); and (3) a copy of any subsequent letter that we issued regarding a GRAS notice would be readily accessible for public review and copying (proposed § 170.36(f)(2)(iii)). In the 2010 notice, we asked for comment on issues relating to what we will do with a GRAS notice as shown in table 18.

TABLE 18—ISSUES IN THE 2010 NOTICE REGARDING WHAT WE WILL DO WITH A GRAS NOTICE

Issue No.	Description of our request for comment	Reference
12	Whether we should make explicit the process by which we make a filing decision, including the factors we would use to determine whether to file a submission as a GRAS notice.	75 FR 81536 at 81541.
14	Whether we should retain a set timeframe for us to respond to a GRAS notice, and, if so, whether it should be 90 days or another timeframe.	75 FR 81536 at 81542.

In the following sections, we discuss comments on what we will do when we receive a GRAS notice. After considering these comments, we are establishing requirements in § 170.265 for what we will do when we receive a GRAS notice as shown in table 19, with editorial, clarifying, and conforming changes as shown in table 29. Table 19 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(d), (e), and (f)(2)(iii) as § 170.265. See section XXV.I for a discussion of comments specific to a filing decision for a substance used in animal food.

TABLE 19—FINAL REQUIREMENTS FOR WHAT FDA WILL DO WITH A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.265(a)(1)	N/A	12	We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use.	N/A.
170.265(a)(2)	170.36(d)	12	If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing.	N/A.
170.265(a)(3)	N/A	12	If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provides our reasons.	Clarifies that we would inform you by letter if we do not file your submission as a GRAS notice.
170.265(a)(4)	N/A	3a	We will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter based on our evaluation of your notice if we deem that doing so is feasible within the established timeframes. If we deem that considering your amendment is not feasible within the established timeframes, or if we have granted your request to cease to evaluate your notice, we will inform you that we are not considering your amendment.	Clarifies that we will only consider an amendment if we deem that doing so is feasible within the established timeframes.
170.265(b)(1)	170.36(e)	14	Within 180 days of filing, we will respond to you by letter based on our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis.	• Specifies that the timeframe for our response is 180 days, rather than 90 days. • Provides for an extension of our evaluation by 90 days on an as needed basis.
170.265(b)(2)	N/A	14	If we extend the timeframe, we will inform you of the change in writing as soon as practicable but no later than within 180 days of filing.	Provides that we will inform you if we extend the timeframe for our response.
170.265(b)(3)	N/A	5	If you ask us to cease to evaluate your GRAS notice, we will send you a letter informing you of our decision regarding your request.	Companion change in light of new regulatory text (in § 170.260(b)) expressly providing that you may ask us to cease to evaluate your GRAS notice.
170.265(c)	170.36(f)(2)(iii)	N/A	If circumstances warrant, we will send you a subsequent letter about the notice.	Clarifies that we may send a subsequent letter, in addition to specifying under the public disclosure provisions of the rule that such a letter would be readily available to the public (see § 170.275(b)(2)).

A. Filing Decision

(Comment 85) One comment asks for greater refinement, clarity, and transparency when we decline to file a GRAS notice. Some comments ask us to communicate any questions or concerns that could be quickly addressed upon submission of a GRAS notice. Another comment asks us to use specific criteria for a "decline to file" determination when format and general categories are adequate. Another comment states that an explicit process for how we will make a filing decision need not be detailed "in the public domain" even though it would be beneficial to the notifier.

Another comment asks us to specify the criteria that we use to decide to provide verbal feedback to a notifier (*e.g.,* by telephone) rather than send the notifier a letter informing the notifier that we have declined to file a submission as a GRAS notice. This comment expresses concern that our refusal to explain the problem in a letter could be interpreted to mean that we have safety concerns. This comment asserts that a process in which we neither provide specific guidance, nor provide written feedback, when we decline to file a submission as a GRAS notice would both discourage voluntary submissions of GRAS conclusions from industry and conflict with GAO's recommendations (in their 2010 report) that we should take steps to increase our awareness of independent conclusions of GRAS status.

(Response 85) These comments raise a number of issues regarding the importance of a written communication from us to a notifier when we decline to file a submission as a GRAS notice, including transparency and the potential that lack of a written explanation for why we declined to file a submission as a GRAS notice could lead to suppositions, such as whether we have safety concerns. To address these issues, the final rule provides that if we do not file a submission as a GRAS notice, we will send the notifier a letter that informs the notifier of that fact and provides our reasons for not filing the submission as a GRAS notice (see § 170.265(a)(3)). We would not place that letter "in the public domain" by including it in our publicly available Inventory of GRAS Notices, because the submission had not been filed as a GRAS notice and, thus, there would be no entry where we would place the letter. However, whether the letter would be releasable in response to a FOIA request would be a case-by-case determination based on the contents of the letter and the provisions of part 20.

We are not specifying in the regulatory text the factors that could lead us to decline to file a submission as a GRAS notice, because the factors that apply to a particular GRAS notice may be very specific to that notice. Importantly, a GRAS notice presents an opportunity for a notifier to inform us about a conclusion of GRAS status rather than an opportunity for a notifier to test a hypothesis that there is a sufficient basis to reach a conclusion of GRAS status. If our initial evaluation of a submission demonstrates that it lacks much of the required data and information necessary for us to evaluate the notifier's view that the notified substance is GRAS under the conditions of its intended use, our current practice is to decline to file it as a GRAS notice (see § 170.265(a)(3)). By declining to file a submission as a GRAS notice, we would both conserve our own resources and provide the notifier an opportunity to submit a new GRAS notice, that contains appropriate data and information and an adequate narrative, rather than move forward knowing that an amendment necessary for us to evaluate the notifier's view that the notified substance is GRAS under the conditions of its intended use would be so substantive as to make the original submission largely irrelevant. For additional examples of factors we have considered in determining whether to file a submission as a GRAS notice, see the examples we provided in the 2010 notice (75 FR 81536 at 81541), the discussion of filing decisions in section III.K of CFSAN's 2010 experience document (Ref. 18), Response 48, and Response 70. As discussed in Response 152, CVM intends to consider the same factors that CFSAN considers regarding whether to file a submission as a GRAS notice.

(Comment 86) In the 2010 notice, we explained that we may decide to respond to a submission as general correspondence, rather than file it as a GRAS notice, if the subject of the submission is: (1) Already authorized for use under our regulations; or (2) a mixture of substances that are already authorized for use under our regulations. One comment asks us to clarify how we would determine that the use of a substance is authorized for use under our regulations, with respect to the similarity of factors such as: (1) The substance; (2) the intended conditions of use of the substance, including food categories and use levels; and (3) the manufacturing process.

(Response 86) We decline this request because it is overly broad. We do not have a "formula" that would apply in all circumstances. Just as the factors that apply to a particular GRAS notice may be very specific to that notice, the factors that would apply in determining whether the intended conditions of use of a notified substance are already authorized by our regulations may be very specific to that substance. However, with regard to similarities in the manufacturing process, we likely would apply the same factors that we have advised industry to apply when assessing the effects of significant manufacturing process changes on the safety and regulatory status of food ingredients (Ref. 6).

We note that we also may decide to respond to a submission as general correspondence, after communicating with the submitter as appropriate, rather than file it for evaluation as a GRAS notice, if the subject of the submission is: (1) Already the subject of a GRAS notice, and we have responded to that GRAS notice with a "no questions letter"; or (2) a mixture of substances that already are the subject of GRAS notices, and we have responded to those GRAS notices with "no questions letters." In contrast to the statutory provisions for the FCN program (section 409(h) of the FD&C Act), there is no provision in the FD&C Act providing exclusivity for a notifier for the use of a substance on the basis that it is GRAS under the conditions of its intended use.

(Comment 87) One comment asks us to conduct a preliminary evaluation of a GRAS notice to determine whether the notice appears to be inadequate because the intended conditions of use of the notified substance raise "general policy" issues.

(Response 87) It is not clear what the comment means by "general policy" issues. However, we note that we would not file a submission as a GRAS notice if the intended conditions of use of the notified substance are not eligible for classification as GRAS because, for example, the intended conditions of use are excepted from the definition of "food additive" in section 201(s) of the FD&C Act (and thus, from the GRAS provision included in that definition of "food additive"). See, for example, the exception for a color additive in section 201(s)(3) of the FD&C Act, for a dietary ingredient intended for use in a dietary supplement in section 201(s)(6) of the FD&C Act, and for a new animal drug in section 201(s)(5) of the FD&C Act.

(Comment 88) Some comments ask us to contact the notifier when our initial evaluation of a GRAS notice raises questions, and provide the notifier with an opportunity to withdraw the notice without prejudice before we begin a substantive evaluation of the notice.

(Response 88) We agree that our decision to not file a submission as a GRAS notice would be without prejudice to a future submission of a GRAS notice for the notified substance. However, see Response 70, Response 112, and the discussion in the 2010 notice at 75 FR 81536 at 81539. Just as a filed GRAS notice is available for public disclosure subject to the procedures established in part 20, a submission that you send to us is a record that is available for public disclosure subject to the procedures established in part 20, regardless of whether we file that submission as a GRAS notice. Thus, you cannot "withdraw" a submission from our files after you send it to us.

(Comment 89) One comment asks whether "substantial equivalence" considerations are linked to "decline to file" decisions or play a dominant role in "decline to file" decisions. This comment also asks us to issue a letter to the notifier explaining the basis for a "decline to file" decision if "substantial equivalence" is the reason.

(Response 89) As discussed in section IV.N of CFSAN's 2010 experience document (Ref. 18), several GRAS notices filed during the Interim Pilot program relied, in part, on the concept of "substantial equivalence"; in each of the listed examples CFSAN had no questions about the notifier's conclusion of GRAS status. As discussed in Response 21, whether, and to what extent, similarity between two substances could support a conclusion of GRAS status depends on many situation-specific variables. Thus, it would be the complete evaluation process, rather than the initial evaluation that we conduct as part of a filing decision, that would determine whether a GRAS notice that relies on the concept of "substantial equivalence" provides a basis for a conclusion of GRAS status. As discussed in Response 85, the final rule provides that if we do not file a submission as a GRAS notice, we will send the notifier a letter that informs the notifier of that fact and provide our reasons for not filing the submission as a GRAS notice (see § 170.265(a)(3)); if problems with a notifier's use of the concept of "substantial equivalence" play a role in our decision to not file a submission as a GRAS notice, we intend to say so.

B. Our Response to a GRAS Notice

1. Administrative Content of Our Response to a GRAS Notice

(Comment 90) Several comments address the administrative content of a letter that responds to a GRAS notice. In general, these comments ask us to include the following items in the response letter: (1) Name and address of the notifier; (2) the date of our receipt of the notice; (3) the common or usual name of the notified substance; and (4) the applicable conditions of use of the notified substance. One comment states that use of a standard format and language in our letters would be administratively efficient.

(Response 90) We agree that a standard format and language in our letters would be administratively efficient and that the administrative features suggested by these comments are appropriate to include in our response letter. During the Interim Pilot program, we both developed a standard format and language for our response letters and included the administrative features suggested by these comments (see section III.H.1 of CFSAN's 2010 experience document (Ref. 18)). We intend to continue incorporating these features in letters issued under the final rule. However, as discussed in Response 51, the final rule requires that you provide the name of the notified substance, using an appropriately descriptive term, rather than the "common or usual name" of the notified substance (see § 170.225(c)(3)). Therefore, CFSAN's response letters will include an appropriately descriptive term for the notified substance provided in a GRAS notice submitted to CFSAN. See section XXV.C regarding the name of the notified substance provided in a GRAS notice submitted to CVM.

2. Substantive Content of Our Response to a GRAS Notice

(Comment 91) Several comments note that the proposed rule did not specify what we would say in a letter responding to a GRAS notice and ask us to include in the final rule the specific language for the response letter, particularly when we do not raise any questions about the notifier's conclusion of GRAS status. Some comments assert that a notifier who invests resources in a GRAS notice deserves a response that is standardized and predictable and will not change as personnel changes occur.

(Response 91) See table 1. During the Interim Pilot program we developed three categories of response letter: (1) "No questions letter"; (2) "insufficient basis letter"; and (3) "cease to evaluate letter." As discussed in sections IV.H.1 through IV.H.7 of CFSAN's 2010 experience document (Ref. 18), these letters include some standard information that is consistent across those letters, such as opening and closing paragraphs using a standard format, and administrative information (*e.g.,* the date of our receipt of the GRAS notice). They also include unique features that depend upon the circumstances, such as labeling issues and whether the use of the substance could require a color additive listing. The content of the three categories of response letter has evolved over time, and may continue to evolve. In addition, it is possible that in the future a response to a GRAS notice may not fit squarely within one of the current categories of response letter. Therefore, the final rule continues to specify that we will respond to a GRAS notice but does not specify any detail about the nature of the response.

(Comment 92) Several comments address the content of a "no questions letter." These comments ask that a "no questions letter" be clear and definitive, provide clear assurance that we recognize the GRAS status of the substance under the conditions of its intended use, have some regulatory significance, and be as affirmative as possible. Some of these comments note that our statements in the proposed rule (62 FR 18938 at 18950) indicated that we would evaluate a GRAS notice to determine whether there is a sufficient basis for the notifier's conclusion of GRAS status and suggest that our response to a GRAS notice could reflect those statements. Comments also suggest the following specific statements that could be included in a "no questions letter":

- "FDA at this time does not question your determination that the notified use(s) of this substance is (are) Generally Recognized as Safe."
- "The Agency finds that there is substantial evidence supporting both the safety of the intended uses of the substance and the fact that this safety is generally known and accepted by qualified experts."
- "The notice provides a sufficient basis for the notifier's determination that the substance is GRAS for its intended use."

(Response 92) See table 1 for the typical text of a "no questions letter" that we issued during the Interim Pilot program. At this time, we intend to continue including such text in our "no questions letters." We agree that the regulatory significance of a "no questions letter" should be clear. As shown in table 1, during the Interim Pilot program a typical "no questions letter" made clear that: (1) It is the information that is provided by the notifier that forms the basis for our response, and that the notifier (rather than FDA) is responsible for the conclusion of GRAS status; and (2) our response must be considered in context based on the knowledge and information available to us at a point in time, because scientific knowledge and information about a particular ingredient can evolve and sometimes change over time.

The typical text of a "no questions letter" issued during the Interim Pilot program is similar to the specific suggestion of one comment (*i.e.,* FDA at this time does not question your determination that the notified use of this substance is GRAS), except that under the final rule we will use the term "conclusion" rather than "determination." We disagree that a "no questions letter" should state that we "find" that there is substantial evidence supporting both the safety of the intended conditions of use of the notified substance and the fact that this safety is generally known and accepted by qualified experts; a GRAS notice reflects the conclusion of the notifier, not a finding by FDA. Likewise, we disagree that a "no questions letter" should state that a notice "provides a sufficient basis" for the notifier's conclusion that the notified substance is GRAS under the conditions of its intended use; the phrase "providing a sufficient basis" would imply that we are taking responsibility for the notifier's conclusion of GRAS status.

As discussed in Response 41, we are replacing the term "determination" with "conclusion," and referring to a "conclusion of GRAS status" rather than to a "GRAS determination," throughout the regulatory text for the GRAS notification procedure. We intend to modify the typical text of our response letters to refer to the "notifier's conclusion" (rather than the "notifier's determination") in letters issued under the final rule (see table 20). We also intend to specify that we have not affirmed the GRAS status of the notified substance under the conditions of its intended use, rather than to specify that we have not made our own determination. However, as noted in section II.B, we intend to adapt our practices, consistent with the provisions of this rule, as circumstances warrant and as necessary to administer the GRAS notification program consistent with appropriate public health policy, current scientific information, our available resources, and the scientific and regulatory issues raised by specific GRAS notices. Thus, the text shown in table 20 is for illustrative purposes only and could evolve over time.

TABLE 20—CATEGORIES OF LETTERS RESPONDING TO A GRAS NOTICE UNDER THE FINAL RULE

Category of response letter	Typical text of for a response as modified to incorporate terms used in the rule
"No questions letter"	Based on the information provided by the notifier, as well as other information available to FDA, the Agency has no questions at this time regarding the notifier's conclusion that the notified substance is GRAS under the conditions of its intended use. By this letter, however, the Agency has not affirmed the GRAS status of the notified substance under the conditions of its intended use in accordance with 21 CFR 170.35. As always, it is the continuing responsibility of the notifier to ensure that food ingredients that the firm markets are safe, and are otherwise in compliance with all applicable legal and regulatory requirements.
"Insufficient basis letter"	FDA has evaluated the data and information in the GRAS notice as well as other available information. The notice does not provide a sufficient basis for a conclusion that the notified substance is GRAS under the conditions of its intended use.
"Cease to evaluate letter"	In correspondence dated [month, day, year], you asked that we cease to evaluate your GRAS notice. We ceased to evaluate your GRAS notice, effective the date we received your correspondence.

(Comment 93) One comment suggests that a written response need not assess the quality of the submission but rather could acknowledge whether the notice was complete in addressing all key issues.

(Response 93) We disagree that we could acknowledge whether a notice is "complete" without assessing the quality of the submission. Providing a basis for whether the data and information regarding the safety of a substance under the conditions of its intended use satisfy GRAS criteria is not a matter of whether there is "something behind each tab." It would not be appropriate, for example, for us to acknowledge that a GRAS notice is "complete" because it included the narrative required by Part 6 of a GRAS notice without assessing the adequacy of the narrative. Whether a notice is "complete" in addressing all key issues depends on the nature and quality of the submitted data and information.

(Comment 94) Some comments ask that a "no questions letter" qualify that we have not affirmed that the intended conditions of use of the notified substance are GRAS. Other comments ask that a "no questions letter" qualify that we have not conducted a substantive review.

(Response 94) We agree that a "no questions letter" should be clear that we have not affirmed that the substance is GRAS under the conditions of its intended use. See table 20.

However, we disagree that a "no questions letter" should state that we did not conduct a substantive review of the GRAS notice. See Response 25. Our evaluation of a GRAS notice is a substantive evaluation of the notifier's basis for concluding that the intended conditions of use of the notified substance are safe and the criteria for GRAS status are satisfied. In addition, as circumstances warrant, we evaluate information that is not included in the notice but is otherwise available to us (see section IV.G of CFSAN's 2010 experience document (Ref. 18)).

(Comment 95) Some comments ask that a "no questions letter" include a positive statement that we have not identified a problem with the notice because finished food producers have been reluctant to use a substance without such documentation. These comments both assert that the only alternative available to manufacturers whose customers require such a positive statement would be to seek food additive approval for an ingredient and maintain that such approval is unnecessary from a legal perspective.

(Response 95) Consistent with the request of these comments, we intend to continue including a statement that we "have no questions at this time" (see table 1 and table 20). Whether a manufacturer's customer requires a regulation prescribing the conditions under which a substance may be safely used in food, when there is a basis for concluding that the substance is GRAS under the conditions of its intended use, is a business matter between the manufacturer and the customer. If the manufacturer submits a food additive petition and we find, based on the data and information submitted in the petition, that the intended conditions of use of the substance are safe, we would issue a regulation prescribing the conditions under which the food additive may be safely used.

(Comment 96) Several comments address the specific content of an "insufficient basis letter" and ask us to be specific about any deficiencies that we identify in the notice. Some comments assert that an "insufficient basis letter" must clearly distinguish between deficiencies that relate to safety and those that relate to a technical matter, such as the level of the substance that is needed to accomplish the intended technical effect. One comment asks us to include in the final rule guidelines that articulate clear standards for issues that are of sufficient magnitude to result in an "insufficient basis letter."

(Response 96) We agree that we should be specific about identified problems and distinguish between circumstances that lead to an insufficient basis letter. Our experience during the Interim Pilot program demonstrates that we have done so, and we intend to continue this practice under the final rule. For example, as discussed in sections IV.H.4 and IV.H.7 of CFSAN's 2010 experience document (Ref. 18), we have issued an insufficient basis letter in cases where health effects seen in toxicological or clinical studies were not adequately explained or because the notice did not describe adequate toxicological studies; when the notice contained insufficient information about dietary exposure; when the notice contained insufficient information to adequately identify the substance; when the notice contained insufficient information to satisfy the standard for demonstration of GRAS status through experience based on common use in food; and as a result of the regulatory framework associated with the substance. To date, we have not issued an insufficient basis letter solely as a result of insufficient evidence regarding the level of the substance that is needed to accomplish the intended technical effect. However, CVM's experience document demonstrates that CVM has included lack of information regarding the intended technical effect as one of several reasons leading to an insufficient basis letter (Ref. 20). Some "no questions letters" issued by CFSAN have discussed the level of the substance that is needed to accomplish the intended technical effect, *e.g.,* when CFSAN informed a notifier who received a "no questions letter" that FSIS needed information regarding the lowest level necessary for the substance to achieve its intended effect in meat, meat food product, or poultry product (see section III.L of CFSAN's 2010 experience document (Ref. 18)).

Our experience during the Interim Pilot program demonstrates that whether a notice provides a sufficient basis for a conclusion of GRAS status is a case-by-case evaluation and that the circumstances vary. Therefore, we decline the request to specify standards for issues that are of sufficient magnitude to result in an "insufficient basis letter." See sections IV.H.4 and IV.H.7 of CFSAN's 2010 experience document (Ref. 18) for information on specific GRAS notices that received an "insufficient basis letter" from CFSAN, and table 1 in CVM's experience document (Ref. 20) for information on GRAS notices that received an "insufficient basis letter" from CVM. Our letters responding to each of these GRAS notices describe the problems in more detail and are available on CFSAN's Web site (Ref. 46) and CVM's Web site (Ref. 47).

(Comment 97) Some comments ask that an "insufficient basis letter" include a qualifying statement that we have not conducted a substantive review and have not concluded that the intended conditions of use of the notified substance are not GRAS. These comments assert that a response that does not include such a statement could have the practical effect of challenging the use of a substance in the absence of a threshold determination that the notified use is not GRAS.

(Response 97) We disagree that an "insufficient basis letter" should state that we did not conduct a substantive review of the GRAS notice. See Response 25 and Response 94. Our evaluation of a GRAS notice is a substantive evaluation.

The typical text of an "insufficient basis letter" specified that "the notice does not provide a sufficient basis" for a determination that the notified substance is GRAS under the conditions of its intended use (see table 1), and we intend to continue including such text in letters issued under the final rule, modified to refer to a "conclusion" of GRAS status rather than a "determination" of GRAS status (see table 20). This typical text addresses the adequacy of the notice rather than the regulatory status of the substance; consistent with the request of these comments, this text does not specify that we have concluded that the intended conditions of use of the notified substance are "not GRAS." In several cases during the Interim Pilot program, a notifier who received an "insufficient basis letter" submitted a second GRAS notice and received a "no questions letter" in response to the second GRAS notice (see sections III.D and IV.K of the experience document (Ref. 18)). In these examples, CFSAN's response to the notifier's first GRAS notice made clear that the submitted notice did not provide a basis for a conclusion of GRAS status, but CFSAN had no questions about the basis for GRAS status provided by the second notice.

3. Our Consideration of a Timely Amendment

As discussed in section XVIII.B, the rule provides that you may submit a timely amendment to your filed GRAS notice to update your GRAS notice or in response to a question from us (§ 170.260(a)). As a companion provision, the rule also provides that we will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice based on our evaluation of your notice if we deem that doing so is feasible within the established timeframes (see § 170.265(a)(4)). If we deem that considering your amendment is not feasible within the established timeframes, we will inform you that we are not considering your amendment (see § 170.265(a)(4)). We also will inform you that we are not considering your amendment if we have granted your request to cease to evaluate your notice (*i.e.,* if we send you a "cease to evaluate letter"). See § 170.265(b)) and Response 98 for the timeframe established in this rule for our response to your GRAS notice.

4. Timeframe for Our Response to a GRAS Notice

(Comment 98) Several comments support retaining the proposed 90-day timeframe. According to these comments, a 90-day timeframe would provide an incentive for a manufacturer to submit a GRAS notice. One comment asserts that we should be held accountable to the proposed 90-day timeframe, whereas another comment suggests that the proposed 90-day timeframe provide a benchmark at which we should make the notifier aware of the current status of our evaluation of the notice even if we have not had sufficient time to completely review the safety of the notified substance.

One comment that asks us to retain the proposed 90-day timeframe stresses that we should have flexibility to take additional time as needed. Another comment agrees that it would be appropriate for us to extend the evaluation period, provided we do so only in limited instances.

One comment asserts that the requirements of the GRAS notification procedure are similar to the requirements of the GRAS affirmation petition process and questions whether we could respond to a GRAS notice within 90 days because we did not respond to a GRAS petition in such a short timeframe. One comment that stresses the importance of retaining a set evaluation timeframe suggests that the timeframe be 90–180 days based on CFSAN's experience during the Interim Pilot program, and opposes a timeframe greater than 180 days. Other comments support a 180-day timeframe because it would be realistic and reasonable, would be sufficient to resolve all of the issues raised by a GRAS notice with procedural fairness, and could be consistent and fair across both CFSAN and CVM.

(Response 98) We are establishing a timeframe of 180 days from the date of filing for our response to a GRAS notice. We also are providing that we may extend the 180-day response timeframe by 90 days on an as needed basis; if we do so, we will inform you of the extension in writing as soon as practicable but no later than within 180 days of filing. (See the regulatory text of § 170.265(b)(1) and (2)). We agree that the 180-day timeframe is realistic and reasonable, would be sufficient to resolve all of the issues raised by a GRAS notice with procedural fairness in most cases, and could be consistent and fair across both CFSAN and CVM.

We disagree that we should establish a 90-day timeframe merely because we had proposed this timeframe before we gained experience with evaluating GRAS notices. As shown in section III.M of CFSAN's 2010 experience document, less than 12 percent of the response letters CFSAN issued as of December 31, 2009, were sent within the proposed 90-day timeframe (Ref.

18). Importantly, section III.M of CFSAN's 2010 experience document also shows that in many cases a dialog between FDA and a notifier about scientific issues associated with a GRAS notice, with an ensuing amendment from the notifier, played a role in the timeframe for CFSAN's response to a GRAS notice. As discussed in the 2010 notice, several comments ask us to allow a notifier to address questions we have about a GRAS notice by submitting an amendment to the notice (see Issue 3a, 75 FR 81536 at 81538), and the final rule expressly provides that you may submit an amendment to a filed GRAS notice before we respond to the notice (see § 170.260(a)). Although we are including flexibility to take additional time as needed, our goal is to do so in only limited instances, such as when the intended conditions of use of the notified substance raise complex scientific issues.

We have no basis to judge whether a 90-day timeframe, but not a 180-day timeframe, would provide an incentive to a manufacturer to submit a GRAS notice. However, as noted in Response 24 CFSAN filed more than 600 GRAS notices during the time period 1998 through 2015, including 69 GRAS notices filed during 2014 and 51 GRAS notices filed during 2015, even though CFSAN rarely responded to a GRAS notice within 90 days. We believe that the ongoing submission of GRAS notices is evidence that the 180-day timeframe that is consistent with our experience during the Interim Pilot program is not a disincentive to a manufacturer.

We note that the procedural requirements of the GRAS notification procedure are very different from the procedural requirements of the GRAS affirmation petition process in that we respond to a GRAS notice by letter whereas we respond to a GRAS affirmation petition through rulemaking. As previously discussed (62 FR 18938 at 18941), the resource-intensive rulemaking process includes: (1) Publishing a filing notice in the **Federal Register**; (2) requesting comment on the petitioned request; (3) conducting a comprehensive review of the petition's data and information and comments received to the filing notice to determine whether the evidence establishes that the petitioned use of the substance is GRAS; (4) drafting a detailed explanation of why the use is GRAS (as opposed to simply being safe); and (5) publishing that explanation in the **Federal Register**. Therefore, we disagree with the perspective of one comment that our experience in responding to a GRAS affirmation petition should have any bearing on the determination of an appropriate timeframe for our response to a GRAS notice.

(Comment 99) One comment expresses concern that a 90-day timeframe would be unrealistic unless we allocate additional resources to the program. This comment asks us to consider a process similar to the process for the FCN program, where there is a fixed review period during which we can "object to" a submitted notification. If we do not object within the review period or do not request an extension to the review period, a notification submitted to the FCN program is considered effective.

(Response 99) We decline this request. We disagree that the GRAS notification procedure should be modeled after the FCN program. Unlike the GRAS notification procedure, the FCN program is a mandatory process for food contact substances under section 409(h) of the FD&C Act. Furthermore, the statute provides that the FCN program shall not operate unless it has certain appropriated funds. See section 409(h)(5)(A)(i) of the FD&C Act and § 170.104(c)(3). There are no similar statutory requirements applicable to our evaluation of the basis for a conclusion of GRAS status.

(Comment 100) One comment asserts that we should respond to a GRAS notice within 90 days unless we identify a problem that warrants dialog with the notifier and an ensuing amendment.

(Response 100) We disagree. The suggestion of this comment could lead to the unintended consequence of seeking unnecessary amendments merely to stay within an established timeframe. We believe it is more appropriate to establish a single timeframe that would broadly apply to all GRAS notices, with the potential to extend the timeframe on an as needed basis.

(Comment 101) One comment asks us to stop the "review clock" when we inform a notifier that we have questions about a notice and then restart the "review clock" upon receipt of an amendment that answers our questions.

(Response 101) We decline this request. We acknowledge that there could be an advantage to such a process, because stopping the review clock would reduce the time pressures on our staff. However, the role of an amendment is to clarify questions that we have about your conclusion of GRAS status rather than to substantively amend the GRAS notice. A process in which we stop and start a review clock implies that the timeframe for you to submit an amendment could be so long as to significantly impact our ability to respond within an established timeframe. Rather than a process in which we stop and start a review clock on a particular GRAS notice, we have provided that you may ask us to cease to evaluate a GRAS notice when your preparation of an amendment would impact our ability to respond within 180 days.

5. Responding to a GRAS Notice in All Circumstances

In the proposed rule, we noted that the GRAS notification procedure could be structured so that we respond only when we question the GRAS status of the intended use of the substance and requested comment on whether we should, in all cases, provide a notifier with a letter at the conclusion of our evaluation of a notice (62 FR 18938 at 18951).

(Comment 102) Several comments agree with our discussion in the proposed rule that a written response from us would give manufacturers an incentive to notify us of their conclusions of GRAS status; these comments recommend that we respond in writing in all circumstances. Other comments suggest that we limit our response to circumstances in which we identify a problem with a notice because such a limitation would make it easier for us to respond within the proposed 90-day timeframe. One comment expresses concern that a written response could create a misperception that we had undertaken an independent review of the data described in the GRAS notice; to prevent this misperception, this comment suggests that we respond in writing only if we find a problem with the notice.

(Response 102) We acknowledge that limiting our response to circumstances in which we identify a problem with a notice would reduce the number of letters that we write. However, we believe that it is important to publicly document our evaluation of the GRAS notice in light of all the comments submitted to this rulemaking. (See, *e.g.,* Comment 25 and the comments we discuss in section VII.C). In addition, in our experience it is the process of evaluating a submission and reaching a decision about whether the notice provides a basis for a conclusion of GRAS status, rather than the process of drafting and issuing a letter, that requires the most time.

We acknowledge the potential that a "no questions letter" could be misinterpreted, *e.g.,* to mean that FDA, rather than the notifier, had reached a conclusion of GRAS status. To mitigate the potential for such misinterpretation, the typical text of our response letters issued during the Interim Pilot program referred to the notifier's determination and stated that we have not made our own determination regarding the GRAS status of the subject use of the notified substance (see table 1). We intend to continue including such typical text in letters issued under the final rule, modified as shown in table 20.

(Comment 103) One comment suggests that we respond in writing only at the notifier's request.

(Response 103) We decline this suggestion, which is contrary to emphasis that the rule places on the notifier's acceptance of responsibility for a conclusion of GRAS status (see the discussion at 62 FR 18938 at 18953).

(Comment 104) One comment asserts that a letter acknowledging receipt of a GRAS notice would constitute a form of response. Another comment suggests that a letter acknowledging receipt of a GRAS notice state whether the notice meets the listed requirements for a GRAS notice, eliminating the need for a second letter responding to the notice when we complete our evaluation. This comment asserts that a second letter would be unnecessary for two reasons. First, the notifier has accepted full responsibility for the conclusion of GRAS status and does not require premarket approval from us. Second, under the terms of the rule a notifier must agree to make all data and information available to us.

(Response 104) The final rule provides that we will inform you of the date on which we filed your notice rather than the date on which we received it, as we had proposed. We disagree that a letter informing you of the date of filing in any way responds to a GRAS notice or should state whether the notice meets the listed requirements for a GRAS notice. As discussed in Response 93, we cannot acknowledge whether a notice "meets the listed requirements" without assessing the quality of the submission, which we do during the evaluation that follows filing the submission as a GRAS notice.

We acknowledge that submitting a GRAS notice means that a notifier has accepted full responsibility for the conclusion of GRAS status. We also acknowledge that the use of a GRAS substance is not subject to our premarket review. However, we disagree that a relevant factor in determining whether we should respond to a notifier is the notifier's agreement to make all data and information available to us if we question whether the notice provides an adequate basis for a conclusion of GRAS status. A GRAS notice presents an opportunity for you to inform us about your conclusion of GRAS status rather than an opportunity for you to test a hypothesis that there is a sufficient basis to reach a conclusion of GRAS status.

(Comment 105) One comment suggests that we issue a written response only when we have reached a conclusion regarding safety.

(Response 105) This comment may have misunderstood the proposed notification procedure. Under the notification procedure, you analyze the available data and information and reach a conclusion about whether the notified substance is safe under the conditions of its intended use and whether there is a basis to conclude that the criteria for GRAS status are satisfied. We evaluate your conclusions regarding the available data and information. During the Interim Pilot program, the typical text of a "no questions letter" stated that we had not reached our own determination regarding the GRAS status of the notified substance under the conditions of its intended use (see table 1).

To the extent that the comment is suggesting that we issue an "insufficient basis letter" when the problem with the notice relates to safety, but not to general recognition, we disagree. It would be inconsistent with the legal basis of the GRAS standard for us to only focus on safety, and we did not do so during the Interim Pilot program. (See section III.A.3 of CFSAN's 2010 experience document (Ref. 18), where CFSAN identifies "insufficient basis letters" in which CFSAN had questions about whether there was general recognition of safety.)

C. Additional Correspondence as Circumstances Warrant

(Comment 106) One comment expresses the view that a "no questions letter" should not affect our ability to change our position if additional information indicates that the use of the substance raises any safety concerns.

(Response 106) We agree, and the final rule expressly provides that we will send the notifier a subsequent letter about the notice if circumstances warrant (see § 170.265(c)). The circumstances may not relate to safety. As discussed in section IV.J of CFSAN's 2010 experience document (Ref. 18), as of December 31, 2009, none of the subsequent letters CFSAN issued during the Interim Pilot program reflected a change in CFSAN's position and several addressed issues other than the safety of the use of the substance. For example, CFSAN issued subsequent letters that: (1) Clarified the intended conditions of use; (2) clarified that the term CFSAN used to refer to the notified substance for the purpose of the letter should not be considered an endorsement of that term for the purpose of declaring the substance in the ingredient statement of food products; (3) clarified FSIS' position regarding the use of the notified substance in meat, meat food product or poultry product; and (4) corrected a mistake in the original response. CFSAN also sent a subsequent letter as an administratively efficient mechanism of responding to a notifier who provided CFSAN with information supporting a conclusion that an additional use of the notified substance satisfied GRAS criteria.

In addition, CFSAN has issued a subsequent letter when CFSAN's first letter was an "insufficient basis letter" rather than a "no questions letter." For example, CFSAN did so when a notifier who received an "insufficient basis letter" submitted a new GRAS notice that did not address the questions CFSAN raised in the "insufficient basis letter." CFSAN also did so when a notifier who received an "insufficient basis letter" submitted a supplement to its original GRAS notice rather than submit a new GRAS notice. See section IV.J of CFSAN's 2010 experience document (Ref. 18).

D. Procedures if a Notifier Disagrees With Our Response

In the proposed rule, we explained that there are existing processes that we considered would be appropriate for a notifier to use to engage us if the notifier disagreed with our response (see 62 FR 18938 at 18952 and table 21). We also noted that any person with concerns about our response to a GRAS notice may contact our Office of the Chief Mediator and Ombudsman; that office works on resolving issues and conflicts that arise in any FDA component.

TABLE 21—EXISTING PROCEDURES IN OUR REGULATIONS THAT CAN APPLY IF A NOTIFIER DISAGREES WITH OUR RESPONSE TO A GRAS NOTICE

Regulatory section (§)	Description
10.25	Initiation of administrative proceedings.
10.33	Administrative reconsideration of action.
10.65	Meetings and correspondence.
10.75	Internal agency review of decisions.

(Comment 107) Several comments express concern that the processes discussed in the proposed rule would be available only after we sent, and made readily accessible to the public, an ''insufficient basis letter.'' Other comments express concern about the practical effect of an ''insufficient basis letter'' on the notifier's ability to market a notified substance while the notifier is seeking review of our evaluation. Some comments ask that our letter be ''stayed'' until any problems that we identified in our response to the notice are resolved under such a process.

(Response 107) We acknowledge the concerns expressed in these comments but are making no changes to the rule to address these concerns. One of the underpinnings of the GRAS notification procedure is that making our response readily accessible to the public will properly underscore your responsibility for the conclusion of GRAS status (62 FR 18938 at 18953). As discussed in Response 104, a GRAS notice presents an opportunity for you to inform us about your conclusion of GRAS status rather than for you to test a hypothesis that there is a sufficient basis to reach a conclusion of GRAS status. If we send you an ''insufficient basis letter,'' we advise you to carefully consider whether marketing the notified substance would be lawful. ''Staying'' an ''insufficient basis letter'' informing you that there may not be a legal basis to market the notified substance, *e.g.,* so that you could market the substance while you are working to resolve the issues that led us to send you an ''insufficient basis letter'', would not change the legal status of the notified substance.

(Comment 108) Several comments assert that the processes we had identified in the proposed rule are cumbersome and do not provide manufacturers with a clear framework or timeline for responding to our questions or concerns. In general, these comments ask us to include in the final rule a prompt, fair, and effective process that would be specific to the GRAS notification procedure. A few comments suggest that such an appeal mechanism also apply to subsequent correspondence from us about a GRAS notice.

Some comments provide specific suggestions for how an appeals mechanism specific to the GRAS notification procedure could work, *e.g.,* by specifying that a notifier may submit additional data and information for our evaluation, or by providing for an independent advisory committee or an FDA-certified third-party review organization to review the matter and issue an opinion. Some comments suggest that an appeals mechanism specify appeal steps and stressed the importance of timeframes for decisions by our officials.

(Response 108) We decline the request to include in the final rule an appeals process that would be specific to the GRAS notification procedure. We agree that the process to contact us about a response to a GRAS notice should be clear. However, we disagree that the existing procedures are unclear, because our regulations fully describe these procedures (§§ 10.25, 10.33, 10.65, and 10.75). We acknowledge that the listed procedures do not provide a clear timeline and that some of the listed procedures (*e.g.,* §§ 10.25 and 10.33) are more cumbersome than others (such as requesting a meeting under § 10.65 or requesting internal Agency review of a decision under § 10.75). In practice during the Interim Pilot program, several notifiers who received an ''insufficient basis letter'' took steps to resolve our questions and subsequently submitted a new GRAS notice or a food additive petition (see the discussion in section III.K of CFSAN's 2010 experience document (Ref. 18)). Given the variety of circumstances that could lead to an ''insufficient basis letter,'' we believe that taking steps to resolve our questions, and submitting a new GRAS notice or a food additive petition, can be an efficient mechanism for you to use in lieu of the procedures we discussed in the proposed rule. Doing so would be consistent with the suggestion of some comments that an appeals mechanism specific to the GRAS notification procedure could include submission of additional data and information for our evaluation, except that the data and information would be submitted in a new GRAS notice rather than be an ''appeal'' to the GRAS notice that received an ''insufficient basis letter.''

We do not have an FDA-certified third-party review organization that could review the matter and issue an opinion. We disagree that convening an independent advisory committee would be appropriate as an additional, routine mechanism to appeal an ''insufficient basis letter.'' Under our regulations in part 14 governing advisory committees, it would be FDA—not a notifier—who decided to convene a meeting of our Food Advisory Committee about the use of a substance in food. We would have little basis to convene a meeting of our Food Advisory Committee as part of an appeal to an ''insufficient basis letter'' unless the notifier had first used one or more of the procedures listed in table 21.

XX. Coordinating Our Evaluation of a GRAS Notice With FSIS

In the 2010 notice, we described some of the terms of a MOU, between FDA and USDA's FSIS, that provides for a coordinated evaluation process with FSIS when the intended conditions of use of a notified substance include use in a product or products subject to regulation by USDA under statutes that it administers (75 FR 81536 at 81541–81542). We also asked for comment on whether to make our coordinated evaluation process with FSIS explicit in the final rule (see Issue 13, 75 FR 81536 at 81541–81542). In 2015, we amended that MOU to include more details about the procedures FDA and FSIS will follow to do so (Ref. 36).

(Comment 109) Comments support coordinating our evaluation of GRAS notices with FSIS and including the procedure for this coordination in the final rule. Comments also support requiring the notifier to provide an additional paper copy that we would send to FSIS as part of this procedure.

(Response 109) The final rule includes procedures for coordinating our evaluation of a GRAS notice with FSIS when the use of the notified substance includes use in a product or products subject to regulation by FSIS under statutes that it administers. (See § 170.270). If you send your GRAS notice on paper, a single paper copy is sufficient; we would send FSIS an electronic copy. (See § 170.210(b) and Response 46). Under § 170.270(d), we will inform you of the advice we receive from FSIS in the letter we send you in accordance with § 170.265(b)(1), as appropriate. By ''as appropriate,'' we mean that in most circumstances we do not intend to provide advice from FSIS about the use of the notified substance when we respond with an ''insufficient basis letter,'' because doing so has the potential to create confusion about the regulatory status of a use of the notified substance in products subject to regulation by FSIS. Likewise, we do not intend to provide advice from FSIS about the use of the notified substance when we respond with a ''cease to evaluate letter'' and, thus, the procedure described in § 170.270(d) does not specify that we will inform you of the advice we receive from FSIS in a letter we send you in accordance with § 170.265(b)(3).

As we noted in section XII.I, this rule does not specify the data and information that FSIS will need to evaluate whether the intended use of the notified substance complies with applicable statutes and regulations, or, if not, whether the use of the substance would be permitted in products under FSIS jurisdiction under specified conditions or restrictions. We recommend that you contact the appropriate staff at FSIS regarding the data and information that FSIS will need you to provide. FSIS provides contact information for its programs on its Web site (Ref. 41).

(Comment 110) One comment agrees that the evaluation of a GRAS notice should be coordinated between FDA and FSIS when "animal products" are involved. This comment notes that FSIS does not currently review the use of a substance intended for use in animal food and recommends that CVM be involved in the safety review process of the notice if the notice involves a substance to be used in animal food.

(Response 110) This comment appears to have misunderstood the purpose of the coordinated evaluation process that we discussed in the 2010 notice. That process applies to the use of a substance in human food products, such as meat and poultry products, that are subject to regulation by USDA and would be evaluated by CFSAN; it does not apply to the use of a substance in animal food. FSIS, under the statutes it administers, does not evaluate a substance intended for use in animal food and, thus, the process would not apply to a GRAS notice received by CVM. See also Response 45.

XXI. Comments on Public Disclosure of a GRAS Notice

We proposed that a "GRAS exemption claim" would be immediately available for public disclosure on the date the notice is received. All remaining data and information in the notice would be available for public disclosure, in accordance with part 20, on the date the notice is received (proposed § 170.36(f)(1)). We also proposed that the following information would be readily accessible for public review and copying: (1) A copy of the "GRAS exemption claim" (proposed § 170.36(f)(2)(i)); (2) a copy of our response letter (proposed § 170.36(f)(2)(ii)); and (3) a copy of any subsequent letter we issued regarding the notice (proposed § 170.36(f)(2)(iii)). In the 2010 notice, we noted that although the decision to submit a GRAS notice would be voluntary, the provisions governing the GRAS notification procedure, including the information to be submitted, would be mandatory (75 FR 81536 at 81540).

In the final rule, you include the signed statements that we proposed be in a "GRAS exemption claim" in Part 1 of your GRAS notice, and we no longer use the term "GRAS exemption claim" (see Response 42). As discussed in Response 50, the final rule stipulates that you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice (see § 170.225(b)).

In the following sections, we discuss comments on the proposed requirements for public disclosure of a GRAS notice. After considering these comments, we are establishing requirements applicable to the public disclosure of a GRAS notice as shown in table 22, with editorial, clarifying, and conforming changes as shown in table 29. (See § 170.275.) Table 22 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(f) as § 170.275.

TABLE 22—FINAL REQUIREMENTS APPLICABLE TO PUBLIC DISCLOSURE OF A GRAS NOTICE

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.275(a)(1)	N/A	N/A	The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice or incorporated into your GRAS notice) are considered a mandatory, rather than voluntary, submission for purposes of its status under the FOIA and part 20.	Clarify that a notice is considered a mandatory, rather than voluntary, submission for purposes of their status under the FOIA and part 20.
170.275(a)(2)	170.36(f)(1)	N/A	The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice or incorporated into your GRAS notice) are available for public disclosure in accordance with part 20 as of the date that we receive your GRAS notice.	Clarify that part 20 applies to amendments and supplements as well as to the GRAS notice as originally submitted.
170.275(b)(1)	170.36(f)(2)(i)	N/A	We will make readily accessible to the public a list of filed GRAS notices, including the information described in the signed statements you include in § 170.225(c)(2) through (c)(5).	Clarifies that the list of submissions that we make publicly available are those that we have "filed" as GRAS notices.
170.275(b)(2)	170.36(f)(2)(ii)	N/A	We will make readily accessible to the public the text of any letter that we issue under § 170.265(b)(1) or (3) (*e.g.,* a "no questions letter" or an "insufficient basis letter"); or under § 170.265(c) (a "subsequent letter").	N/A.
170.275(b)(3)	170.36(f)(2)(ii)	N/A	We will make readily accessible to the public the text of any letter that we issue under § 170.265(b)(3) (*e.g.,* a "cease to evaluate letter").	Clarify that the provisions in which we make certain letters readily accessible to the public apply to a "cease to evaluate letter".

TABLE 22—FINAL REQUIREMENTS APPLICABLE TO PUBLIC DISCLOSURE OF A GRAS NOTICE—Continued

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.275(c)	170.36(f)(2)(iii)	N/A	We will disclose public information in accordance with part 20.	N/A.

A. Data and Information in a GRAS Notice Are Available for Public Disclosure on the Date That We Receive It

(Comment 111) One comment asserts that the releasability of the contents of a GRAS notice should be governed by § 20.111 (data and information submitted voluntarily to us) because the FD&C Act does not require submission of a GRAS notice. The comment asserts that § 20.111 would affect the releasability of the content of a GRAS notice in three ways. First, while a GRAS notice is pending, § 20.111 would protect from disclosure safety data or information about an ingredient under development. Second, § 20.111 would permanently protect from disclosure any data or information relating to manufacturing, production or sales, or formulas. Third, § 20.111 would establish that a notifier has the right to request that we evaluate the notifier's position that specific data or information in a GRAS notice are protected from disclosure because these data or information fall within the exemption in § 20.61 for trade secrets and commercial or financial information, which is privileged or confidential.

(Response 111) We disagree that the provisions of § 20.111 apply to a GRAS notice. Although your decision to submit a GRAS notice is voluntary, the information included in your GRAS notice is required. To make that clear, the final rule stipulates that the data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice or incorporated into your GRAS notice) are considered a mandatory, rather than voluntary, submission for purposes of its status under the FOIA and part 20 (see § 170.275(a)(1)).

We agree that a notifier has a right to request that we evaluate the notifier's position that specific data or information in a GRAS notice are protected from disclosure because these data or information fall within the exemption in § 20.61 for trade secrets and confidential commercial information. See § 170.225(c)(8), which requires that you state your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the FOIA.

(Comment 112) Several comments assert that a GRAS notice should not be publicly available until after we have completed our evaluation. These comments also assert that a delay in disclosure, coupled with an opportunity for a notifier to amend the notice, would: (1) Avoid the release of information that we deemed to be inadequate or incomplete; and (2) avoid release of a notice that was withdrawn if coupled with an opportunity for a notifier to withdraw a notice.

(Response 112) We disagree that we should refrain from disclosing the existence of a GRAS notice, or the contents of a GRAS notice, until after we have completed our evaluation. As previously discussed, immediate disclosure of a GRAS notice underscores a notifier's responsibility for a conclusion of GRAS status (62 FR 18938 at 18953). As discussed in Response 2, immediate disclosure of a GRAS notice also provides an opportunity for outside parties to make us aware of dissenting views about whether the available data and information support a conclusion that the notified substance is safe under the conditions of its intended use, and we did receive information from outside parties during the Interim Pilot program. Continuing to provide an opportunity for public participation is consistent with our substitution of the GRAS notification procedure for the former GRAS affirmation petition process, in which there was a public comment period.

As discussed in Response 83, our current regulations regarding public information stipulate that no person may withdraw records submitted to FDA (see § 20.29), and those regulations will apply to a GRAS notice that you to ask us to "cease to evaluate."

(Comment 113) One comment asks us to make a GRAS notice available for public disclosure only after we accept the submission for review. Some comments contrast our proposal for immediate disclosure of a GRAS notice with the provisions of: (1) The GRAS affirmation petition process, in which a GRAS affirmation petition is disclosed only after the petition has been accepted for filing (former § 170.35(c)(2)); and (2) the health claim petition process, in which a health claim petition becomes available for public disclosure only after it is filed and a health claim petition that is denied without filing is not available for disclosure (21 CFR 101.70(j)).

(Response 113) The final rule continues to specify that the data and information in a GRAS notice are available for public disclosure as of the date of receipt (see § 170.275(a)(2)). The former GRAS affirmation petition process did not specify when a submitted GRAS affirmation petition would be available for public disclosure. Instead, the former GRAS affirmation petition process merely specified that we would place the petition on public file in the office of the Division of Dockets Management and publish a notice of filing in the **Federal Register** within 30 days after the date of filing. In addition, we disagree that the public disclosure provisions in § 101.70(j) applicable to the health claim petition process should apply to the GRAS notification procedure. Those provisions derive directly from the statutory provisions that direct the health claim program (section 403(r)(4)(A)(i) of the FD&C Act (21 U.S.C. 343(r)(4)(A)(i))).

Under § 20.103, with few exceptions all correspondence from members of the public, organization or company officials, or other persons, is available for public disclosure at the time that we receive it unless a different time for such disclosure is specified in other rules established or cross-referenced in part 20. As noted in Comment 86 and Response 86, we may decide to file and respond to a submission as general correspondence, rather than as a GRAS notice, in certain circumstances; if we do so, the data and information in the submission would be available as of the date of receipt. Retaining date of receipt as the timeframe for when a submission you transmit as a GRAS notice is available for public disclosure is both consistent with § 20.103 and a practical approach to a situation in which we receive a FOIA request for a GRAS submission before we have determined whether to file the submission as a GRAS notice. As a practical matter, we believe that such situations will be rare, and that in most cases a GRAS submission will be disclosed after we have determined whether to file it and evaluate it as a GRAS notice, or to file it and respond to it as general correspondence.

(Comment 114) Some comments disagree with the assumption we stated in the proposed rule (62 FR 18938 at 18952) that submission of a GRAS notice would not reflect the notifier's plans about the timing or the use of the substance in a marketed product, because a GRAS substance may be marketed without prior approval.

(Response 114) We acknowledge that immediate disclosure of a GRAS notice could, in certain circumstances, provide information about the timing of market entry. However, when the data and information regarding the safety of the substance under the conditions of its intended use satisfy GRAS criteria, neither the law nor this rulemaking would prevent you from marketing a substance before submitting a GRAS notice or during our evaluation of that notice.

B. We Will Make a List of Filed GRAS Notices and Our Responses to GRAS Notices Readily Accessible

(Comment 115) Several comments address our stated intention to maintain an inventory of GRAS notices that we receive, our response, and any subsequent relevant correspondence. (See the discussion at 68 FR 18938 at 18953.) Some of these comments agree with the discussion in the proposed rule that an inventory of GRAS notices should be an adjunct to the proposed rule rather than be included in the regulatory text. Other comments disagree and ask us to include the creation and availability of the inventory in the regulatory text. These comments assert that a provision that merely states that the inventory exists and is available for public review would address the concern that we identified in the proposed rule about the need to maintain flexibility regarding our administration of the inventory.

(Response 115) The final rule specifies that we will make the following readily accessible to the public: (1) A list of filed GRAS notices, including the information described in certain of the signed statements that are included in Part 1 of a GRAS notice (*i.e.,* § 170.225(c)(2) through (c)(5)); and (2) The text of any letter that we issue under § 170.265(b)(1) (our response to a GRAS notice based on our evaluation of the notice), § 170.265(b)(3) (a letter if we grant a request that we cease to evaluate a GRAS notice), or § 170.265(c) (a subsequent letter that we send about a GRAS notice). (See § 170.275(b).) We are not specifying that the mechanism for us to do so is through an "Inventory" because the procedure we used to make this information readily accessible to the public evolved over time during the Interim Pilot program, and may continue to evolve (see section III.I.1 in CFSAN's 2010 experience document (Ref. 18)).

(Comment 116) In the proposed rule, we stated our intention to initially maintain a paper version of an inventory at our Dockets Management Branch (now Division of Dockets Management) and asked for comment on making an inventory available through electronic means such as the Internet (62 FR 18938 at 18953). Comments support maintaining an inventory in paper format, electronic format, or both formats so that all members of the public could have ready access to such information regarding GRAS notices. Some comments point out that electronic access would be particularly important to the international food industry. Some comments support the Division of Dockets Management as the best location for an inventory maintained in paper format.

(Response 116) As discussed in section III.I.1 in CFSAN's 2010 experience document (Ref. 18), the procedure we used to make this information readily accessible to the public evolved over time during the Interim Pilot program. It began as a paper file (first maintained at the Division of Dockets Management, and then maintained in the public reading room of our Freedom of Information Staff), and evolved into its current electronic format on our Internet site (Ref. 46). We intend to continue using the Internet as the principal means to make the inventory readily accessible because doing so is an efficient and effective mechanism to disseminate information to anyone who has access to the Internet. The inventory on the Internet can be accessed and printed from computers in the public reading room at Division of Dockets Management, as well as from computers located at businesses, at homes, and at public locations such as libraries and Internet cafes. If a person either does not have access to the Internet or chooses not to access the inventory through the Internet, that person can request each GRAS notice, and each letter listed in § 170.265(b)(1) or (3) or (c), under the FOIA. It is no longer practical for us to maintain a paper file at the Division of Dockets Management, because all new information sent to the Division of Dockets Management is maintained electronically; paper submissions are scanned to electronic form.

(Comment 117) One comment that addresses the discussion in the 2010 notice about the reasons that may lead us to decline to file a submission as a GRAS notice, such as when the use is covered by an existing regulation, asks us to include those submissions in the GRAS inventory so there will be no confusion as to the status of the ingredient.

(Response 117) We decline this request. The purpose of the inventory of GRAS notices is to provide a list of all the GRAS notices that we have filed and evaluated, not to interpret the uses listed in our regulations or, as discussed in Response 86, covered by an existing GRAS notice.

(Comment 118) A few comments suggest that a publicly available inventory of GRAS notices could suffice to document that certain notices raised no significant issues.

(Response 118) We agree that a publicly available inventory of GRAS notices can document which notices result in a "no questions letter, *e.g.,* by prominently listing the category of our response. The Inventory of GRAS Notices developed during the Interim Pilot program prominently classifies each response letter as "no questions," "insufficient basis," and "cease to evaluate" (Ref. 46). However, we disagree that merely displaying the category of our response, without providing the full text of a letter that places that category of response in context, is appropriate, regardless of whether the response to the GRAS notice is "no questions," "insufficient basis," or "cease to evaluate." For example, even when we answer "FDA has no questions," our response letter highlights key safety considerations, such as the importance of ensuring that the method of manufacture removes potential contaminants.

(Comment 119) One comment asks us to provide "public notice" of all GRAS notices and the information provided therein. Another comment asks us to make the "GRAS exemption claim" readily accessible to the public by publishing information that would be in the publicly accessible file in the **Federal Register** in addition to placing the "GRAS exemption claim" in a readily accessible file. This comment states that doing so would provide the public with access to as much information as possible about what substances would be used in food on the basis of the GRAS provision if FDA is going to "forgo its role" in the evaluation of the safety of GRAS substances. This comment also asks us to publish the receipt of the notice and all of our subsequent responses to the notice in the **Federal Register**.

Another comment asks us to publish semi-annually, either in a **Federal Register** notice or by regulation, a list of GRAS notices that receive a "no questions letter" in addition to posting the Inventory of GRAS notices on our Web site. This comment explains that questions are sometimes raised—especially from outside the United States—about the regulatory status of a substance used in food on the basis of the GRAS provision unless that use of the substance is either incorporated into the CFR or otherwise officially published. This comment asserts that periodic publications in the **Federal Register** would assist in addressing this concern.

(Response 119) By specifying that we will make a list of filed GRAS notices readily accessible (currently, through the inventory on the Internet), the rule requires us to actively disclose those GRAS notices. There is a gap between the date on which we receive a GRAS notice and the date on which we add it to the inventory, *e.g.,* CFSAN currently updates its inventory on an approximately monthly basis. However, in practice during the Interim Pilot program there was ample public notice of the receipt of the GRAS notice before CFSAN responded to it (see the discussion of the timeframe for CFSAN's response in section III.M of CFSAN's 2010 experience document (Ref. 18)). In addition, the rule provides that we may send a subsequent letter about the GRAS notice if circumstances warrant; such circumstances could include data and information, received from a member of the public, after we responded to the GRAS notice.

We decline the requests to provide public notice through an announcement in the **Federal Register**. Publishing an announcement in the **Federal Register** requires an expenditure of our resources (including time and cost of publication) that would be inconsistent with our goal of using our resources efficiently and effectively. Even if we conserved resources by publishing such a notice only on a semi-annual basis, we disagree that "officially publishing" a list of GRAS notices that receive a "no questions letter" in the **Federal Register** would address concerns, in the domestic or international community, about the regulatory status of the use of a substance when that use is not listed in our regulations. It is the Code of Federal Regulations, not the **Federal Register**, that is the official repository of our regulations listing authorized uses of food substances.

We disagree that we are forgoing our role in the evaluation of the safety of substances used in food on the basis of the GRAS provision. See Response 25.

(Comment 120) One comment asks us to place the entire GRAS notice, rather than only the proposed "GRAS exemption claim," in a readily accessible paper file, *e.g.,* at the Division of Dockets Management. In the comment's view, a simple provision that a notifier submit one additional paper copy would mitigate our concerns about the administrative inefficiency of maintaining duplicate files at both the center and Agency levels. Another comment asks us to make the entire notice readily accessible in electronic form.

(Response 120) We currently make a hyperlink to an electronic copy of each GRAS notice accessible from within the entry for that GRAS notice in the inventory, after appropriate redaction (*e.g.,* of privacy information, copyrighted material, and any data and information that are exempt from public disclosure) (Ref. 18, footnote 3). As a practical matter, placing paper files on public display requires space, which is finite, and our Division of Dockets Management scans paper submissions into electronic format.

C. Public Disclosure of a GRAS Notice Is in Accordance With Our Public Information Regulations in Part 20

(Comment 121) One comment agrees that information submitted under the proposed "GRAS exemption claim" should exclude from public disclosure the non-public confidential information with the exception of safety data.

(Response 121) This comment appears to have misinterpreted the proposed provisions regarding submission of non-public information and how the public disclosure provisions of this rule apply to non-public information. The proposed "GRAS exemption claim" is the precursor of Part 1 of a GRAS notice (which we are establishing in § 170.225). The rule specifies that you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice, except in the statement of your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the FOIA. Part 1 of a GRAS notice includes signed statements and a certification, not "safety data." The "safety data" would be included in Parts 2 through 7 of the GRAS notice. Consistent with the view of this comment, the rule provides that those data and information are available for public disclosure upon receipt (see § 170.275(a)(2)). See also Response 50.

(Comment 122) Some comments ask us to alert the notifier, and grant the notifier an option to withdraw the notice, in order to protect information designated as confidential from disclosure.

(Response 122) We decline this request. A person who submits a record to us may not withdraw that record from our files (§ 20.29). Rather, the procedures that govern the release of information that a notifier identifies as confidential in a GRAS notice are established in §§ 20.61 and 20.27. Under § 20.61(d), a person who submits records to us may designate part or all of the information in such records as exempt from disclosure under exemption 4 of FOIA. However, under § 20.27 marking records submitted to us as confidential, or with any other similar term, raises no obligation by FDA to regard such records as confidential, to return them to the person who has submitted them, to withhold them from disclosure to the public, or to advise the person submitting them when a request for their public disclosure is received or when they are in fact disclosed.

XXII. Submission of a Supplement

The rule provides that you may submit a supplement to a GRAS notice after we respond to your notice based on our evaluation of your notice or cease to evaluate your notice (§ 170.280). However, if our response to your GRAS notice raises questions about your conclusion that the notified substance is GRAS under the conditions of its intended use, the appropriate mechanism for you to address those questions would be to submit a new GRAS notice or other regulatory submission (such as a food additive petition) rather than to submit a supplement. See section III.C.2 of CFSAN's 2010 experience document for examples of supplements that CFSAN received during the Interim Pilot program (Ref. 18).

XXIII. Comments on the Administrative Process for Pending GRAS Affirmation Petitions

We proposed that any pending petitions would be presumptively converted to a GRAS notice on the date the final rule becomes effective (proposed § 170.36(g)(1)). An affected petitioner would have an opportunity to amend the converted petition to meet the requirements of the GRAS notification procedure by submitting a

“GRAS exemption claim” (proposed § 170.36(g)(2)). A GRAS affirmation petition that is converted to a notice and that the affected petitioner amends would be reviewed and administered according to the provisions of the GRAS notification procedure; the date of receipt of the amendment would be the date of receipt of the notice (proposed § 170.36(g)(3)(i)). After 90 days from the date of publication of the final rule, we would inform any affected petitioner who had not amended an applicable petition that the converted petition is inadequate as a GRAS notice.

In the 2010 notice, we requested comments on three issues related to the pending petitions as shown in table 23. Although the 2010 notice classified all of these issues as “Issue 17,” for presentation purposes in this document we classify the three issues as 17a, 17b, and 17c.

TABLE 23—ISSUES IN THE 2010 NOTICE REGARDING PENDING GRAS AFFIRMATION PETITIONS

Issue No.	Description of our request for comment	Reference
17a	How to reduce the impact on affected petitioners while retaining the principle that we will not devote resources to pending petitions.	75 FR 81536 at 81542–81543.
17b	Whether an outcome of “withdrawal without prejudice” instead of “insufficient basis” would be more appropriate when an affected petitioner simply chooses not to have the pending petition considered under the GRAS notification procedure.	75 FR 81536 at 81542–81543.
17c	Whether an affected petitioner could request that we incorporate into a GRAS notice a withdrawn GRAS affirmation petition into a GRAS notice, and if so, if any requirements of the GRAS notification procedure should be waived.	75 FR 81536 at 81542–81543.

In the following paragraphs, we discuss comments regarding the disposition of pending petitions in light of the deletion of the GRAS affirmation petition process. After considering these comments, we are establishing provisions for the pending petitions as shown in table 24, with editorial, clarifying, and conforming changes as shown in table 29. (See § 170.285.) Table 24 identifies changes we made relative to the proposed rule or the description in the 2010 notice other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of proposed § 170.36(g) as § 170.285.

TABLE 24—FINAL REQUIREMENTS FOR DISPOSITION OF PENDING GRAS AFFIRMATION PETITIONS

Final designation in the regulatory text (§)	Proposed designation in the regulatory text (§)	Issue No. in the 2010 notice	Description	Revisions (other than editorial, clarifying, and conforming changes) relative to the proposed rule or the 2010 notice
170.285(a)	170.36(g)(1)	17a and 17b	On the effective date of the rule, we will close the docket for any GRAS affirmation petition that is still pending as of that date.	We administratively close the docket for the GRAS affirmation petition rulemaking rather than convert the pending petition to a GRAS notice.
170.285(b)	170.36(g)(2)	17c	Any person who submitted a GRAS affirmation petition that is pending as of the date of the final rule may submit a GRAS notice and request that we incorporate the GRAS affirmation petition.	The affected petitioner submits a GRAS notice rather than an amendment to a “converted petition”.
N/A	170.36(g)(3)(i)	N/A	N/A	No longer specifies the procedures for FDA’s evaluation of a former pending petition.
N/A	170.36(g)(3)(ii)	17a and 17b	N/A	No longer treats a pending petition that is not evaluated as a GRAS notice as having an insufficient basis to support GRAS status.

(Comment 123) Some comments to the proposed rule support our proposal to convert pending GRAS affirmation petitions to GRAS notices on the effective date of the rule. However, as discussed in the 2010 notice, many comments to the proposed rule object to our proposal for administering the pending petitions as being fundamentally unfair, because an affected petitioner had invested considerable time and resources in the petition process and should not be penalized by our adoption of a new GRAS notification procedure. Some of these comments state that, in most cases, FDA also had dedicated significant resources to the review of these petitions and, in some cases, had even arranged for an additional third party to review the substance that was the subject of the petition. These comments suggest options such as “grandfathering” pending petitions, *i.e.*, completing the rulemaking process for them, particularly if we had completed our scientific review with no outstanding questions. Some comments ask us to provide an affected petitioner 180 days, rather than 90 days, to amend the converted petition to satisfy the requirements of the GRAS notification procedure. One of these comments argues that there need not be any urgency in closing the applicable files because many of these petitions had been pending for years, and the subjects of the petitions had been marketed during those years.

Some comments to the proposed rule assert that more resources would be needed to review a petition that is converted to a GRAS notice than would be needed to complete the review of each pending petition and issue a regulation. One comment suggests that it would be simpler and more efficient administratively to allow an affected petitioner an option to update a GRAS affirmation petition to include additional conditions of use or new specifications than to require separate GRAS notices for such changes.

Other comments ask us to clarify the procedures we would use to convert a GRAS affirmation petition to a GRAS notice as well as procedures for amending a petition that was converted to a GRAS notice through an additional submission. Some comments assert that we should not require an affected petitioner to submit such an amendment because all of the pertinent information would already be included in the petition and argue that technical adherence to the format of a GRAS notice should not take precedence over administrative efficiency and common sense. Other comments express concern that it was not clear that the proposed additional submission (proposed § 170.36(g)(2)) was in fact a skeleton notice that primarily would cross-reference the original GRAS affirmation petition.

Some comments to the 2010 notice suggest that a pending petition could be "withdrawn without prejudice" or "suspended" so that it would no longer require FDA resources to review it. Other comments to the 2010 notice express the view that a simple letter of conversion should be adequate, but that if an affected petitioner chose not do so then the outcome of the converted petition would more appropriately be described as "withdrawn without prejudice" rather than "insufficient" as a GRAS notice. Other comments to the 2010 notice continue to express the view that we should "grandfather" a pending petition. One of these comments asserts that failure to grandfather those affirmation petitions where FDA had completed its review and no outstanding scientific issues exist would be unfair because the GRAS notification procedure results in a lower level of authoritativeness than the GRAS affirmation petition process, and the affected petitioners had invested considerable time and resources in the petition process. This comment also notes that after we published the proposed rule we continued to review GRAS affirmation petitions and completed the process for six GRAS affirmation petitions before discontinuing further activity in 1999. Comments that address Issue 17c recommend that an affected petitioner be allowed to incorporate information from a "withdrawn" GRAS affirmation petition into a GRAS notice.

We received no comments asking us to waive any of the requirements of the notification procedure.

(Response 123) We have revised the proposed provisions regarding the disposition of pending petitions in light of the concern of the comments that the proposed process was unfair to affected petitioners. The final rule provides that on the effective date of the rule, we will close the docket for any GRAS affirmation petition that is still pending as of that date (§ 170.285(a)). Any person who submitted a GRAS affirmation petition that is pending as of the date of the final rule may submit a GRAS notice and request that we incorporate the GRAS affirmation petition (§ 170.285(b)). We are closing the docket for the petition by operation of law because the process that would be necessary to bring a petition to closure (*i.e.,* § 170.35(c)) no longer exists. We decided to close the docket for the petition, rather than classify the petition as withdrawn without prejudice, for two reasons. First, closing the docket is an administrative option that is open to us, whereas in our petition processes withdrawing a petition is an option that falls to the petitioner (see, *e.g.,* § 171.1(j) for withdrawal of a food additive petition without prejudice). Second, "withdrawal without prejudice" generally means "without prejudice to a future filing," and "future filing" refers to the same type of filing; however, we have eliminated the GRAS affirmation petition process and, thus, an affected petitioner could not submit another GRAS affirmation petition.

Closing the docket is neutral with respect to a conclusion by an affected petitioner that the petitioned substance is GRAS under the conditions of its intended use, because closing the docket does not result in a publicly available "insufficient basis letter." To clarify that closing the petition is without prejudice to eligibility for classification of the use of the substance as GRAS, the final rule specifically provides that an affected petitioner may incorporate the former GRAS affirmation petition into a GRAS notice. Given the passage of time since the pending petitions were submitted, it is likely that some of the data and information in the petition would need to be updated. In addition, the affected petitioner would need to follow all format requirements for a GRAS notice, including the narrative required in Part 6 of a GRAS notice.

We acknowledge that our response to a GRAS notice does not have the same level of "authoritativeness" as a listing in our regulations. However, some of the comments that objected to the proposal to convert a pending petition to a GRAS notice assert that the substances that are the subject of the pending petitions have been marketed for years; clearly, these affected petitioners are able to market the substance without a listing in our regulations.

We agree that it is appropriate to extend the timeframe for an affected petitioner to take action with respect to a pending petition. Under final § 170.285(b), there is no limit on the timeframe for an affected petitioner to submit a GRAS notice that incorporates a GRAS affirmation petition.

We decline the request to "grandfather" any pending petitions. We simply do not have sufficient resources to devote to the rulemaking process that is required for GRAS affirmation, regardless of whether we already have completed our scientific review. For example, even if we have completed our scientific review, the Administrative Procedures Act (5 U.S.C. 553) requires that we consider relevant data, views, or arguments submitted to us by interested persons and that we publish a concise general statement of the basis and purpose of the regulation. In addition, Executive Order 12866 requires that we assess the costs and benefits of available regulatory alternatives when we conduct rulemaking, and the Regulatory Flexibility Act (5 U.S.C. 601–612) requires that we consider alternatives that would minimize the economic impact of our regulations on small entities. Thus, to complete the rulemaking associated with the GRAS affirmation petition process, we require significant resources beyond those associated with scientific review. Even if we did "grandfather" a pending petition, it is highly unlikely that we would be able to devote resources to this voluntary process in light of competing programs that are required by statute. For example, the resources that could be directed to the GRAS affirmation petition process must be considered together with the resources that are required to administer the food and color additive petition processes and the premarket notification process for food contact substances, which are required programs under sections 409 and 721 of the FD&C Act.

For the reasons discussed in the previous paragraph, we disagree that we would have needed more resources to review a petition that is converted to a GRAS notice than to complete the review of each pending petition and issue a regulation. We also disagree that it would be simpler and more efficient administratively to allow an affected petitioner an option to update a GRAS affirmation petition. As discussed in CFSAN's 2016 experience document (Ref. 19), during the 10-year period extending from 1990 through 1999, CFSAN completed the rulemaking process for 24 GRAS affirmation petitions, with an average elapsed time of approximately 7.9 years (median elapsed time approximately 6.9 years). In contrast, under the final rule we will respond to a GRAS notice in 180 days, with an option to extend the timeframe by an additional 90 days (see Response 98).

As of August 17, 2016 there are 45 pending GRAS affirmation petitions. We intend to contact each affected petitioner to inform the petitioner that: (1) We are closing the affected docket as of October 17, 2016; and (2) the petitioner may submit a GRAS notice that incorporates the former GRAS affirmation petition.

(Comment 124) One comment asks us to issue a regulation, to be included in part 184, that lists the pending petitions. The comment also asks us to include a statement that the lack of an affirmation regulation does not indicate that FDA disagrees with the affected petitioner's GRAS determination.

(Response 124) We decline this request. Our regulations in part 184 represent our own conclusions regarding the GRAS status of a listed substance under the conditions of its intended use. It is inappropriate for our regulations to become a catalog of circumstances where we have not reached our own conclusion regarding GRAS status.

However, under final § 170.275(b), we will make a list of filed GRAS notices readily accessible to the public. The inventory of GRAS notices that currently makes this list available includes a link to information about each listed GRAS notice. When the GRAS notice was originally submitted as a GRAS affirmation petition, we have included the petition number. We intend to continue this practice under the final rule.

We also have placed a list of the pending petitions that we are closing in the docket for this rule (Ref. 48).

XXIV. Other Comments

A. GRAS Panels and Conflict of Interest

In the 2010 notice, we explained that the GAO report noted that we have not issued any conflict of interest guidance that companies can use to help ensure that the members of their expert panels are independent (75 FR 81536 at 81542). The GAO report recommended that we develop a strategy to minimize the potential for conflicts of interest, including taking steps such as issuing guidance for companies on conflict of interest and requiring information in GRAS notices regarding expert panelists' independence. In the 2010 notice, we requested comments on three issues related to GAO's recommendation regarding conflict of interest as shown in table 25. Although the 2010 notice classified all of these issues as "Issue 15," for presentation purposes in this document we classify the three issues as 15a, 15b, and 15c.

TABLE 25—ISSUES IN THE 2010 NOTICE REGARDING GUIDANCE ON CONFLICT OF INTEREST

Issue No.	Description of our request for comment	Reference
15a	Whether companies would find it useful to have guidance on potential conflicts of interest of GRAS expert panelists.	75 FR 81536 at 81542.
15b	If guidance on potential conflicts of interest of GRAS expert panelists would be useful, what companies currently do to mitigate such a conflict.	75 FR 81536 at 81542.
15c	Whether to require that GRAS notices include information regarding expert panelists' independence	75 FR 81536 at 81542.

(Comment 125) Most of the comments that addressed Issues 15a and 15b ask us to provide guidance regarding potential conflicts of interest of GRAS panel members. One of these comments provided an example of a draft guidance for our consideration. Other comments provide criteria that they ask us to consider in the guidance. One comment asks us to provide an opportunity for industry, academia, and the public to comment on our proposed course of action for the topic of conflict of interest.

One comment asserts that there is no need for guidance regarding potential conflicts of interest of GRAS panel members because industry is aware of the importance of disclosing and addressing potential conflicts of interest and often has Standard Operating Procedures delineating rules for disclosure.

(Response 125) We have decided to issue guidance regarding conflict of interest. We will do so as Level 1 guidance within the framework of our good guidance practices regulation (see § 10.115(c) and (g)). Under that framework, we prepare a draft of Level 1 guidance and then: (1) Publish a notice in the **Federal Register** announcing that the draft guidance document is available; (2) post the draft guidance document on the Internet and make it available in hard copy; and (3) invite public comment on the draft guidance document. After providing an opportunity for public comment on a Level 1 guidance document, FDA will: (1) Review any comments received and prepare the final version of the guidance document that incorporates suggested changes, when appropriate; (2) publish a notice in the **Federal Register** announcing that the guidance document is available; (3) post the guidance document on the Internet and make it available in hard copy; and (4) implement the guidance document. We will consider the recommendations and draft guidance submitted in the comments to this rule in developing our draft guidance for public comment.

We acknowledge that some members of industry are aware of the importance of disclosing and addressing potential conflicts of interest. However, we disagree that this awareness means that we should not issue a guidance regarding conflict of interest. A guidance from us on conflict of interest could promote consistency in addressing conflict of interest by different companies.

(Comment 126) One comment notes that an external GRAS panel is not required for a conclusion of GRAS status when the conclusion is supported by peer-reviewed literature or a "long history of safe use." (By "long history of safe use," we assume that the comment is referring to the provision that GRAS criteria may be satisfied through experience based on common use in food prior to January 1, 1958. See § 170.30(a) and (c)).

(Response 126) We agree that an external GRAS panel is not required for a conclusion of GRAS status. As we previously noted, convening a GRAS panel has historically been a way to provide evidence that generally available data and information are generally accepted by the expert scientific community, but convening a GRAS panel is not the only way to provide such evidence (62 FR 18938 at 18943).

(Comment 127) Some comments address Issue 15c and recommend that a notifier include information on independence of the panel members in a submitted GRAS notice.

(Response 127) The rule neither requires that a notifier convene a GRAS panel nor establishes any other requirements applicable to a GRAS panel. Therefore, we are addressing issues regarding a GRAS panel in guidance rather than in the regulation. See also Comment 14 and Response 14.

B. Guidance on Documenting Conclusions of GRAS Status

In the 2010 notice, we explained that the GAO report recommended that we issue guidance on how to document a conclusion of GRAS status (75 FR 81536 at 81542). We noted that there is guidance in the preamble to the proposed rule and in our guidance for industry entitled "Frequently Asked Questions About GRAS" (Ref. 49). We requested comments on two issues related to guidance on documenting a conclusion of GRAS status as shown in table 26. Although the 2010 notice classified both of these issues as "Issue 16," for presentation purposes in this document we classify the two issues as 16a and 16b.

TABLE 26—ISSUES IN THE 2010 NOTICE REGARDING GUIDANCE ON DOCUMENTING GRAS CONCLUSIONS

Issue No.	Description of our request for comment	Reference
16a	Whether there is a need to clarify that our guidance applying to GRAS submissions also applies to a GRAS conclusion that is not submitted to us in the form of a GRAS notice.	75 FR 81536 at 81542.
16b	Whether there is a need for us to develop further guidance on documenting a GRAS conclusion when the GRAS conclusion is not submitted to us as a GRAS notice.	75 FR 81536 at 81542.

(Comment 128) Most of the comments that addressed Issue 16a recommend that we clarify that the same standards apply to a conclusion of GRAS status regardless of whether the conclusion is submitted to us as a GRAS notice or is not submitted to us.

(Response 128) To reach a conclusion of GRAS status, the proponent of GRAS status must: (1) Establish that the substance is safe under the conditions of its intended use within the meaning of section 409(c)(5) of the FD&C Act and our implementing regulation in § 170.3(i); and (2) establish that the safety of the substance under the conditions of its intended use is generally recognized within the meaning of section 201(s) of the FD&C Act and our regulations in § 170.30 governing the eligibility for classification as GRAS. See the discussion in section I.C of the proposed rule of the elements of the GRAS standard, where we described the evaluation of safety as the "technical element" of the GRAS standard and the evaluation of general recognition as the "common knowledge element" of the GRAS standard. In considering whether GRAS criteria are satisfied because the available data and information demonstrate that the use of a substance is safe and the safety is generally recognized, we do not distinguish between a conclusion of GRAS status submitted to us as a GRAS notice and an independent conclusion of GRAS status that remains with the proponent. As discussed in Response 41, in this rulemaking we made conforming changes to current regulations regarding the use of GRAS substances in food, and our affirmation of GRAS status on our own initiative, to emphasize that point (see the changes to §§ 170.3(i) and (k), 170.30(c), 170.30(e), and 170.35(a) and (b) in table 29). As already noted in section I.E of this document, we advise any company that intends to market a food substance on the basis of an independent conclusion of GRAS status to carefully consider whether this use fully satisfies the criteria for eligibility for classification as GRAS and to carefully review the discussions in this document relevant to those criteria, such as the discussion in Response 9 regarding the role of corroborative data and information, the discussions in Response 10 and Response 11 regarding the limitations of a published report of a GRAS panel, and the discussion in Response 69 regarding the ramifications of providing trade secret information (or other non-public information) to a GRAS panel.

Our 2004 guidance entitled "Frequently Asked Questions About GRAS" generally applies to a conclusion of GRAS status regardless of whether that conclusion of GRAS status is submitted to us as a GRAS notice. Exceptions include current questions specific to the notification procedure as it operated during the Interim Pilot program, such as "Where do I send my GRAS notice?" We are modifying that guidance to update it in light of the publication of this rule.

We believe that the provisions of the GRAS notification procedure in part 170, subpart E will be a useful resource to any person who intends to use a substance in food based on a conclusion of GRAS status, regardless of whether the conclusion of GRAS status is submitted to us in a GRAS notice or is an independent GRAS conclusion that is not submitted to us. For example, the requirements in Part 3 of a GRAS notice make clear that a conclusion of GRAS status requires consideration of dietary exposure. Likewise, the requirements in Part 6 of a GRAS notice demonstrate the importance of a complete and balanced evaluation of all applicable data and information, including data and information that are, or may appear to be, inconsistent with a conclusion of GRAS status. Therefore, we recommend that any person who intends to use a substance in food based on a conclusion of GRAS status, but does not intend to submit a GRAS notice to us, use the provisions of part 170, subpart E as guidance. We also recommend that such persons organize the data and information that support an independent conclusion of GRAS status according to the organization presented by Parts 1 through 7 of a GRAS notice. Doing so would facilitate our evaluation of that independent conclusion of GRAS status if circumstances warrant, *e.g.*, if we have cause to question the independent conclusion of GRAS status. Because we make information about GRAS notices readily accessible to the public, we also recommend that you make the basis for your independent GRAS conclusion publicly available (*e.g.*, by making publicly available a document analogous to the narrative of a GRAS notice, a report of a GRAS panel (if you convene a GRAS panel), or both a narrative and a report of a GRAS panel).

General recognition of safety based upon scientific procedures requires the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient (§ 170.30(b)). We address scientific issues associated with demonstrating the safety of a food substance in a series of guidance documents on our Internet (Ref. 6, Ref. 25, and Ref. 32 through Ref. 35). Currently, some of these scientific guidance documents are expressly directed to evaluation of the safety of food additives. For example, in Response 66 we noted that our guidance entitled "Recommendations for Submission of Chemical and Technological Data for Direct Food Additive Petitions" (Ref. 31) currently is structured to address the specific requirements of a food additive petition, even though many of the recommendations in that guidance could nonetheless be useful to any person who evaluates whether a substance is GRAS under the conditions of its intended use. As resources allow, we intend to re-visit these scientific guidance documents to determine whether and how to modify them to clarify that our guidance on evaluating the safety of a food substance generally applies regardless of whether the substance would be used in food as a food additive or as a GRAS substance. Regardless of any implication, in the title or text of these guidance documents, that the subject of the document applies to a food additive, we recommend that you consider that the scientific recommendations in these guidance documents may also apply to substances that would be used in food on the basis of a GRAS conclusion.

Some scientific guidance documents already do make clear that they apply regardless of the regulatory status of a substance (*e.g.,* as a food additive, color additive, food contact substance, or GRAS substance) (Ref. 6). In addition, as discussed in Response 37, we recently issued a notice announcing a public meeting, and requesting comments, on our intent to update our guidance entitled "Guidance for Industry and Other Stakeholders: Toxicological Principles for the Safety Assessment of Food Ingredients" (79 FR 64603), and reiterated that general recognition of safety based upon scientific procedures requires the same quantity and quality of evidence as is required to approve a food additive.

(Comment 129) Some comments support issuing additional guidance on documenting a conclusion of GRAS status, particularly for a GRAS conclusion that is not submitted to us. One comment asserts that there is no need for us to develop additional guidance on documenting a conclusion of GRAS status that is not submitted to us. One comment agrees with the recommendation in the GAO report that we take steps to ensure that companies maintain proper documentation to support a conclusion of GRAS status.

(Response 129) We agree that companies should maintain proper documentation to support a conclusion of GRAS status. As we discussed in the proposed rule (62 FR 18938 at 18947), any person who concludes that a substance is GRAS under the conditions of its intended use should have assembled and evaluated the evidence that forms the basis of that conclusion, regardless of whether the person subsequently notifies us. Preserving the applicable data and information represents prudent practice for those who assert that the statutory premarket review requirements do not apply to the use of a substance in food.

To emphasize the importance of maintaining the data and information that support an independent conclusion of GRAS status, we are issuing a guidance directed to any person who evaluates whether the available data and information regarding the safety of a substance under the conditions of its intended use satisfy GRAS criteria. The purpose of the guidance is to: (1) Remind such persons of their responsibilities under the FD&C Act regarding a conclusion of GRAS status, regardless of whether the conclusion of GRAS status is submitted to us as a GRAS notice; and (2) refer such persons to key resources, such as those discussed in Response 128, for evaluating the safety of the substance under the conditions of its intended use and for evaluating whether the available data and information regarding safety satisfy the criteria for eligibility for classification as GRAS in § 170.30. We believe that such guidance is appropriate in light of the recommendations of the GAO report.

C. Compliance With Other FDA Regulations

We proposed that a GRAS notice would not constitute compliance with the requirements for a health claim petition in § 101.14(b)(3)(ii) or for a new infant formula submission in § 106.120(b)(6)(ii). We specified that any person who submits a health claim petition, or who submits a new infant formula submission, must comply in full with the requirements of the applicable program (proposed § 170.36(a)(2)).

(Comment 130) Several comments object to the perceived implication that a GRAS notice could never be used to support a health claim petition or a new infant formula submission. In general, the comments maintain we should consider, on a case-by-case basis, whether a particular GRAS notice is sufficient to comply with the requirements of the applicable program rather than categorically disallow a GRAS notice as a means for satisfying the requirements of the applicable program.

(Response 130) We are not including this proposed provision in the final rule because it is not necessary to do so. Any person who submits a health claim petition, or who submits a new infant formula submission, must comply in full with the requirements of the applicable program whether this rule says so or not. An FDA office that evaluates a health claim petition or a new infant formula submission will take into account our response to a GRAS notice when evaluating the health claim petition or new infant formula submission. In practice during the Interim Pilot program, an FDA office evaluated a health claim petition or a new infant formula submission for several substances that were the subject of a previously submitted GRAS notice. In each case, FDA's evaluation of the health claim petition or new infant formula submission had an outcome that was consistent with our response to that GRAS notice (see section IV.A of CFSAN's 2010 experience document (Ref. 18)).

D. Impact on Other Federal Agencies

In our discussion in the proposed rule of the proposed procedures for making information about GRAS notices readily accessible to the public, we stated our belief that there would be considerable interest, from a broad segment of the public, including other Federal agencies, in notices received under the proposed notification procedure (62 FR 18938 at 18952). We also stated our expectation that such groups will likely want to know whether we are aware that a substance is being used in food on the basis of the GRAS provision and whether we have advised a notifier that we have identified a problem with the notice.

(Comment 131) The Bureau of Alcohol, Tobacco and Firearms (BATF) (in the U.S. Department of the Treasury (now TTB) submitted a comment stating that it has no major problem with our proposal to replace the GRAS affirmation petition process with a notification procedure, but that there are two ways in which the proposed rule would impact TTB. First, TTB's wine regulations in 27 CFR 24.250 (Application for use of new treating material or process) require that a proprietor who wishes to use a new wine treating material submit to TTB an application that includes documentary evidence of FDA's approval of the material under the conditions of its intended use. If we issue a final rule to establish a GRAS notification procedure, TTB would need to amend this requirement to state that TTB needs either evidence of FDA approval or evidence that FDA has been notified of a conclusion of GRAS status and has no questions about that conclusion.

Second, certain alcoholic beverage products require formula approval by TTB due to the ingredients (such as colors, flavors, herbs, and spices) in the products. Currently, TTB requires that these ingredients be approved by FDA before TTB approves the formula. If we issue a final rule to establish a GRAS notification procedure, TTB would still check the ingredients in these formulas before approving the formula, but could accept evidence that FDA has been notified of a conclusion of GRAS status and has no questions about that conclusion.

TTB asks us to include the conditions of use in our response to a GRAS notice so that TTB would know the parameters that FDA evaluated in considering the GRAS notice (*i.e.,* the foods and beverages and the amounts in those foods and beverages). TTB also asks us to publish and update a list of GRAS notices on a frequent basis, and to include the conditions of use that FDA evaluated in this list.

(Response 131) The provisions of this rule are consistent with TTB's requests. The rule specifies that we will make a list of filed GRAS notices, including the information described in § 170.225(c)(2) through (c)(5), readily accessible to the public (see § 170.275(b)(1)). The information the rule specifies will be readily accessible includes the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purpose(s) for which the substance will be used (see § 170.225(c)(4)). The response letters that we issued during the Interim Pilot program described the conditions of use of the notified substance, and we intend to continue describing the conditions of use of the notified substance in letters issued under the final rule.

(Comment 132) Some comments assert that our affirmation of GRAS status established a clear standard that was needed by other Federal agencies to carry out their own regulatory responsibilities. The comments cite BATF (now TTB), FSIS (in USDA), and EPA as examples of such Federal agencies. In general, these comments maintain that the applicable Federal agency must be able to accept our response to a GRAS notice in lieu of a regulation affirming GRAS status. One comment notes that the proposed rule did not explicitly address the impact of the proposed rule on other Federal agencies and urges us to consult with the cited Federal agencies prior to issuing the final rule.

(Response 132) None of the Federal agencies cited by these comments have advised us that the absence of a regulation affirming GRAS status for the use of a food substance would preclude the applicable Agency from carrying out its statutory responsibilities. As discussed in the following paragraphs, we have interacted with each of these agencies as requested.

TTB. As discussed in section IV.B of CFSAN's 2010 experience document (Ref. 18), during the Interim Pilot program CFSAN received and filed several GRAS notices for substances intended for use in alcoholic beverage products. These notices demonstrate that manufacturers of alcoholic beverage products are aware of the GRAS notification procedure and are using GRAS notices as a means to satisfy TTB's regulations. As also discussed in section IV.B of CFSAN's 2010 experience document (Ref. 18), on September 29, 2005, representatives of TTB met with representatives of CFSAN in the offices of CFSAN's Office of Food Additive Safety. At that meeting, representatives of CFSAN described the GRAS notification procedure that was operating under the framework of the proposed rule. CFSAN provided a copy of TTB's comments to these representatives, and none of TTB's representatives expressed any concern about the operation of the program.

FSIS. As discussed in section III.L of CFSAN's 2010 experience document (Ref. 18), during the period 1998 through 2009 more than 25 percent of GRAS notices filed by CFSAN described use of the notified substance in meat, meat food products, or poultry products. During CFSAN's review of these GRAS notices, CFSAN consulted with FSIS regarding the use of the applicable substance. FSIS provided feedback to CFSAN about the use of the notified substance in products regulated by FSIS and requested that CFSAN provide this feedback to the notifier. In 2000, FDA and FSIS formalized this process of inter-agency consultation in a MOU (65 FR 33330, May 23, 2000). Subsequently, FDA and FSIS have amended the MOU to include simultaneous evaluation of substances subject to regulation by USDA under the Egg Products Inspection Act (21 U.S.C. 1033(a)(2)) (Ref. 36). The final rule includes the procedures CFSAN will use when coordinating its evaluation of a GRAS notice with FSIS (see § 170.270).

EPA. CFSAN has discussed the concerns raised by these comments with representatives from EPA (Ref. 50). The representatives from EPA deferred to CFSAN regarding the appropriate process for voluntary interaction between us and the regulated industry with respect to GRAS substances.

E. Impact on International Trade

In the proposed rule, we requested comment on whether the proposed substitution of a GRAS notification procedure for the GRAS affirmation petition process would have any impact on international trade (62 FR 18938 at 18955).

(Comment 133) Comments that responded to this request for comment express the view that whether the proposed substitution of a GRAS notification procedure for the GRAS affirmation petition process would have a positive, neutral, or negative impact on international trade would depend on the nature of our response to a GRAS notice, particularly when we do not question the notifier's basis for a conclusion of GRAS status. The comments explain that the proposed rule could have a positive or neutral impact on international trade if our response is clear and definitive, provides regulatory significance, and is as affirmative as possible, but could have a negative impact on international trade if our response is neutral or vague. One comment expresses the opinion that any impact on international trade would be minimal because JECFA frequently assesses uses of a food ingredient, and foreign regulatory agencies frequently reach a decision to allow uses of a food ingredient, before we complete our rulemaking under the GRAS affirmation petition process.

(Response 133) The "no questions letters" we issued during the Interim Pilot program make clear that the notifier (rather than FDA) is responsible for the conclusion of GRAS status, and place our statement that we have no questions about the notifier's conclusion of GRAS status in the contexts of both time and the available data and information (see table 1). These features of the "no questions letters" make the letters clear and definitive and provide regulatory significance (*i.e.,* regulatory status), and we intend to retain these features in letters we issue under the final rule. Moreover, the fact that many GRAS notices were submitted by foreign firms demonstrates that foreign firms see value in submitting GRAS notices to us (Ref. 51).

Under the final rule, we will respond to a GRAS notice within 180 days after we file a submission as a GRAS notice, with an option to extend the timeframe by an additional 90 days as needed (see § 170.265(b)(1)). As discussed in Response 123, during the ten year period extending from 1990 through 1999, we completed the rulemaking process for 24 GRAS affirmation petitions, with an average elapsed time of approximately 7.9 years (median elapsed time approximately 6.9 years). Thus, we believe that the GRAS notification procedure will come to closure more quickly than the GRAS affirmation petition process.

F. Audits

In the proposed rule, we stated that it would be prudent for us monitor compliance with the essence of the statutory requirements for GRAS status (*i.e.,* that there is common knowledge among qualified experts that there is reasonable certainty that the substance is not harmful under the conditions of its intended use) and announced that we intended to conduct random audits of data and information maintained by the notifier (62 FR 18938 at 18947). In addition, because the proposed substitution of a GRAS notification procedure for the GRAS affirmation petition process would allow us to direct our resources to priority questions about GRAS status, we might conduct an audit on a broad issue or class of products if the issue or use of a class of products raises important public health issues.

(Comment 134) One comment asks us to renew our commitment to random auditing to ensure that companies maintain proper recordkeeping practices.

(Response 134) As discussed in section IV.C of CFSAN's 2010 experience document (Ref. 18), during the Interim Pilot program, CFSAN did not conduct any random audits of data and information maintained by the notifier. However, CFSAN did not hesitate to ask a notifier to provide certain data or information as an amendment to a GRAS notice. (See also the discussion in section III.C.1 of CFSAN's 2010 experience document regarding amendments to GRAS notices.) In essence, CFSAN used its resources to seek access to data and information on a priority, rather than a random, basis. At this time, we intend to continue directing our resources on a priority basis under the final rule.

(Comment 135) One comment asks us to provide a notifier with the option of converting a GRAS notice to a GRAS affirmation petition if we audit the data supporting a GRAS notice.

(Response 135) As discussed in Response 24 and Response 123, we have eliminated the former GRAS affirmation petition process. Therefore, the administrative process requested by these comments is no longer operative.

(Comment 136) One comment asks us to incorporate two procedures to avoid any uncertainty regarding the results of the audit. First, the comment asks us to provide the notifier with a letter confirming that the audit is completed and we have no basis to question the conclusion of GRAS status if that is the outcome of our audit. Second, the comment asks us to apply any appeal mechanism specified by the rule to circumstances in which we question a conclusion of GRAS status based on an audit.

(Response 136) We decline these requests. If we have no questions about the notifier's conclusion of GRAS status, we would respond with a ''no questions letter'' based on our evaluation of the entire GRAS notice, not based solely on the results of an audit of the data and information maintained by the notifier to support the notifier's GRAS notice. As discussed in Response 108, the rule does not include an appeals process that would be specific to the GRAS notification procedure.

(Comment 137) One comment suggests that our audit examine the same ''quantum of evidence'' as we would review to affirm GRAS status, and asserts that a strong statement of confidence, if not outright affirmation, would be appropriate after successful completion of this type of an indepth review.

(Response 137) The purpose of the audit would be to verify that a notifier maintains the data and information specified in the notice, not to conduct a full scientific evaluation of those data and information (62 FR 18938 at 18947). Therefore, we decline the request to examine the same ''quantum of evidence'' as we would review to affirm GRAS status. Because the purpose of an audit would be to verify compliance with the statutory requirements for GRAS criteria, we disagree our response to a GRAS notice following a favorable audit should result in a ''strong statement of confidence'' rather than a ''no questions letter.'' However, we intend that our response letter would mention any audit that we conduct before responding to a GRAS notice.

G. Lack of an Environmental Assessment

(Comment 138) One comment suggests that a GRAS notice is ideal in circumstances where our evaluation of an environmental assessment, which is required for a food additive petition, precludes timely action by us on a petition.

(Response 138) We advise potential notifiers that the lack of a requirement to submit an environmental component (*e.g.,* an environmental assessment) with a GRAS notice does not eliminate a notifier's responsibility to comply with applicable Federal, State, tribal, and local law or requirements regarding protection of the environment.

H. Substances Affirmed as GRAS With Specific Limitations

(Comment 139) One comment asks us to ''modernize the standard'' in § 184.1(b)(2) to allow expedited review under the notification program of new uses of substances affirmed as GRAS under § 184.1(b)(2). (Section 184.1(b)(2) specifies that if an ingredient is affirmed as GRAS with specific limitation(s), it shall be used in food only within such limitation(s), including the category of food(s), the functional use(s) of the ingredient, and the level(s) of use, and any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.)

(Response 139) We decline the request to amend § 184.1(b) beyond the editorial, clarifying, and conforming changes listed in table 29. The comment provides no basis for us to do so. As discussed during the rulemaking to establish § 184.1(b)(2) (41 CFR 53600 at 53601, December 7, 1976), that regulation does not require that a subsequent use be covered by a food additive regulation even though it may be GRAS. As an alternative to a food additive regulation, the regulation affirming a substance as GRAS with specific limitations on the conditions of use may be amended to cover additional uses that have become GRAS. Importantly, both mechanisms (*i.e.,* food additive regulation and GRAS affirmation regulation) require rulemaking, and the appropriate mechanism for a manufacturer to lawfully use a substance outside the limitations established in a regulation affirming specific uses of the substance as GRAS with specific limitations is to submit a petition to us. A manufacturer may submit a food additive petition asking us to conduct rulemaking that results in a food additive regulation; alternatively, now that the GRAS affirmation petition process is no longer operative, the manufacturer may submit a citizen petition in accordance with § 10.30 asking us to conduct rulemaking that amends the regulation affirming a substance as GRAS with specific limitations on the conditions of use. (See also Ref. 4.58 to CFSAN's 2010 experience document).

See section III.N.2 of CFSAN's 2010 experience document (Ref. 18) for a discussion of a GRAS affirmation petition to amend a specific regulation that affirmed a substance as GRAS with specific limitations on the conditions of use; we converted that GRAS affirmation petition to a food additive petition and authorized the additional conditions of use in a food additive regulation. We advise persons who wish to petition us to provide for additional uses of substances that have been affirmed as GRAS with specific limitations that under § 10.30(e) we may advise that we are denying the request to initiate rulemaking to amend the GRAS affirmation regulation, but note that we could accommodate the request to conduct rulemaking through the food additive petition process.

XXV. Comments on Substances Intended for Use in Animal Food

A. Issues in the 2010 Notice Specific to Animal Food

In the 2010 notice, we discussed several issues associated with the requirements for a GRAS notice for an intended use in animal food to consider dietary exposure (see table 27). Although we discussed these issues in a section entitled "Dietary exposure," these issues broadly applied to several provisions of the rule (see, *e.g.*, §§ 570.30, 570.225(c)(4), 570.235, 570.245, and 570.250). In the following sections, we discuss how comments on these issues, and associated conforming changes, lead to specific revisions to the regulatory text. See table 28 for the principal changes specific to the proposed animal food rule other than the editorial, clarifying, and conforming changes shown in table 29 and the additional editorial changes associated with the redesignation of the proposed notification procedure (proposed § 570.36) as part 570, subpart E. Table 28 does not include those changes that we made to the proposed requirements when we made an analogous change to the human food regulations in part 170.

TABLE 27—ISSUES IN THE 2010 NOTICE SPECIFIC TO ANIMAL FOOD

Issue No.	Description of our request for comment	Reference
11c	Whether it is necessary to clarify that the GRAS notification procedure is applicable to substances used in both food and drinking water of animals and, if so, whether it would be necessary to clarify this in the provisions of the proposed notification procedure.	75 FR 81536 at 81541.
11d	Whether it is necessary to clarify proposed § 570.36(c)(1)(iii) to explicitly require submission of information about the animal species expected to consume the substance.	75 FR 81536 at 81541.
11e	Whether it is necessary to clarify applicable sections of the proposed rule to explicitly require, for substances intended for use in the food of an animal used to produce human food, the submission of information about both target animal and human safety.	75 FR 81536 at 81541.

TABLE 28—SUMMARY OF PRINCIPAL CHANGES SPECIFIC TO THE PROPOSED ANIMAL FOOD RULE

Regulatory section in the final rule	Change
§ 570.30(a), (b), and (c)	Specify that general recognition of safety is based on data and information that addresses safety for both the target animal and for humans consuming human food derived from food-producing animals.
§ 570.225(c)(4)	Requires you to describe the intended conditions of use of a notified substance in animal food by specifying the levels of use in foods or drinking water.
§ 570.235	In part 3 of your GRAS notice, you must provide data and information about exposure to the target animal and to humans consuming human food derived from food-producing animals.
§ 570.250(a) and (b)	You must explain how the generally available data and information in your notice provide a basis for your view that the notified substance is generally recognized as safe, among qualified experts, under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals.

B. Criteria for Eligibility for Classification as GRAS for a Substance Intended for Use in Animal Food (§ 570.30)

(Comment 140) Comments that address Issue 11e agree that data and information in a GRAS notice must be sufficient to address safety for both the target animal and for humans consuming human food derived from food-producing animals (see Comment 150 and Comment 151).

(Response 140) We have modified several provisions of the GRAS notification procedure to specify how the notifier must provide data and information to address the safety of the notified substance under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals (see §§ 570.225(c)(4), 570.235, 570.245, and 570.250). To clarify that the submission requirements reflect the GRAS criteria for the use of a substance in animal food, we also have modified § 570.30(a), (b), and (c) to specify that general recognition of safety is based on data and information that addresses safety for both the target animal and for humans consuming human food derived from food-producing animals. See the regulatory text of § 570.30. See also Response 141 regarding the definition of common use in food in § 570.3(f).

(Comment 141) One comment notes that the proposed human food regulations, but not the proposed animal food regulations, include specific criteria for eligibility for classification as GRAS through experience based on common use in food prior to 1958 when that use occurred exclusively or primarily outside the United States (see § 170.30(c)(2)). This comment asks us to maintain parallel criteria for eligibility for classification as GRAS through experience based on common use in food in the human food regulations and the animal food regulations by amending § 570.30(c) of the animal food regulations to include a provision analogous to § 170.30(c)(2).

(Response 141) We are amending § 570.30(c) to include a provision analogous to § 170.30(c)(2). See the regulatory text of § 570.30(c)(1) and (2). For consistency with the clarifying amendment to the general criteria in § 570.30(a), we also are revising § 570.30(c) to clarify that general recognition of safety through experience based on common use in food shall address safety for both the target animal and for humans consuming human food derived from food-producing animals. For consistency with the clarifying amendment to the general criteria in § 570.30(a), we also are revising the definition of common use in food to mean a substantial history of consumption of a substance by a significant number of animals of the species to which the substance is intended to be fed (and, for food-producing animals fed with such substance, also means a substantial history of consumption by humans consuming human foods derived from those food-producing animals), prior to January 1, 1958 (see § 570.3(f) and table 29).

C. Part 1 of a GRAS Notice for a Substance Intended for Use in Animal Food: Name of the Notified Substance (§ 570.225(c)(3))

As shown in table 6, in the 2010 notice we asked for comment on whether to require that the GRAS notice include the name of the notified substance, using an appropriately descriptive term, instead of the "common or usual name" of the notified substance (Issue 7). The final rule requires that Part 1 of a GRAS notice for an intended use of a notified substance in animal food include the name of the notified substance, using an appropriately descriptive term (§ 570.225(c)(3)). The appropriately descriptive term may be the same as the common or usual name of the substance. You may consult with CVM's staff in operating divisions that address the labeling requirements of the FD&C Act, currently CVM's Division of Animal Feeds, regarding any common or usual name for a substance used in animal food. In addition, for substances used in animal food, the Association of American Feed Control Officials (AAFCO) annually publishes its Official Publication, a handbook which contains, among other things, Official Feed Terms, which define many of the terms commonly used in the animal food manufacturing industry. It also contains Official and Tentative Definitions of Feed Ingredients, a set of definitions for ingredients commonly used in animal food. Under CVM's Compliance Policy Guide CPG 665.100 (Common or Usual Names for Animal Feed Ingredients), the definitions, as they appear in the AAFCO Official Publication, are generally regarded as constituting the common or usual name for animal food ingredients, including pet food (Ref. 52).

D. Part 1 of a GRAS Notice for a Substance Intended for Use in Animal Food: Intended Conditions of Use (§ 570.225(c)(4))

(Comment 142) One comment asks us to require that a notifier specify whether the intended use of the notified substance is in food or in drinking water. Another comment asks CVM to accept the anticipated consumption levels by animals that are based upon general formulation principles that consider the availability of contemporary feedstuffs.

(Response 142) The final requirements for Part 1 of a GRAS notice require you to describe the intended conditions of use of a notified substance in animal food by stating whether the substance will be added to food (including drinking water) for animals in which the substance will be used, and by identifying the foods to which it will be added and the levels of use in such foods (see § 570.225(c)(4)). In describing the levels of use of the notified substance, you may base the levels of use upon general formulation principles that consider the availability of contemporary feedstuffs. See also Response 148 regarding the calculation of target animal exposure.

(Comment 143) Some comments ask us to specifically require submission of information about the animal species expected to consume the substance. One comment states that specifying the target animal is as important as specifying whether the substance would be consumed by humans in human food derived from the animal. Another comment suggests that requiring submission of information about the animal that would consume the substance would avoid the unnecessary delays associated with CVM's questions that result in an amendment to the notice with information about the animal species expected to consume the substance.

(Response 143) The final requirements for Part 1 of a GRAS notice require you to describe the intended conditions of use of a notified substance in animal food, including the animal species for which the foods are intended. In addition, the final requirements for Part 1 of a GRAS notice specify that in describing the intended conditions of use of a notified substance in animal food, you must, when appropriate, describe any "subpopulation" expected to consume the notified substance; the life stage of an animal is an example of what we mean by "subpopulation." The physical, physiologic, and absorption/distribution/metabolism/elimination characteristics of a given animal species may vary based on life stages within the same animal species. A substance that is safe for use in an animal species at one stage of life may not be safe for use in the same animal species at a different stage of life. See also Response 51.

E. Part 2 of a GRAS Notice for a Substance Intended for Use in Animal Food: Data and Information Bearing on the Physical or Other Technical Effect of the Notified Substance (§ 570.230(d))

(Comment 144) Several comments discuss CVM's practice, during the Interim Pilot program, of asking a notifier to provide data or information demonstrating the effectiveness, or utility, of the substance. Some comments ask us to limit the notification procedure to the information necessary to conduct an appropriate safety assessment, without submission of additional data and information to demonstrate the technical effect of the substance within animal food in cases where the technical effect has no impact on safety. Some comments agree that the intended conditions of use of the notified substance in animal food must be described and supported in the notice, but assert that the need for utility data generated from target animal feeding studies is inappropriate and unnecessary because the pivotal issue is whether the ingredient is safe to feed to animals.

(Response 144) We have added a requirement for Part 2 of a GRAS notice to include relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect, when necessary to demonstrate safety (see § 570.230(d)). We agree that data and information bearing on the physical or other technical effect the notified substance is intended to produce are only necessary when they bear on safety. This relationship to safety is consistent with the requirements of the FD&C Act for a petition to establish the safety of a food additive (see section 409(b)(2)(C) of the FD&C Act).

The physical or other technical effects of substances added to animal food fall into two main categories: (1) Substances fed for a nutritive effect in the animal (*e.g.,* providing one or more nutrients or other nutritive effect); and (2) substances that have technical effects in the food (*e.g.,* anti-caking agents, binders, emulsifiers, enzymes, mixing aids, preservatives, processing aids, stabilizers, and substances added for aroma, flavor, or other technical effects) rather than nutritive effects in the animal. As discussed in the following paragraphs, a substance added for either a nutritive effect or for a technical effect in animal food can have an impact on safety for the target animal.

Nutritive effect in the animal. Data and information bearing on the nutritive effect of a substance may be necessary to demonstrate safety because animals (*e.g.,* food-producing animals, companion animals) typically are fed the same diet formula for long periods of their life. These diets are formulated to supply all of the animal's daily nutrient needs for a specific life stage (*e.g.,* growth, reproduction, adult maintenance). The diet must provide appropriate amounts of all nutrients the animal requires in a form that the animal can use and consume daily; otherwise, a nutrient deficiency or toxicity can result, causing adverse effects to animal health, including poor growth, excessive weight loss, organ system failures, and death. Under these constraints of how animals are fed, a substance intended to provide one or more nutrients becomes unsafe if the nutrients are, in fact, not provided in a form usable by the animals consuming the diet.

The typical approach to support the nutritive effect of a substance intended for use in animal food is to combine generally available and accepted data and information about the general function of the substance with animal feeding studies demonstrating that the substance acts as intended. When an appropriate animal feeding study (*i.e.,* an animal feeding study that is relevant, properly designed, and well-controlled) is already generally available (*e.g.,* in the peer-reviewed scientific literature), it can be possible to support the nutritive effect of a substance without conducting a new study. If an appropriate animal feeding study is not already generally available, an animal feeding study specifically conducted to support the nutritive effect would ordinarily be published and, as discussed in Response 19, there would be a time gap between the publication of the study and the use of the published study to support a conclusion of GRAS status. (As discussed in Response 9, unpublished studies can be used to corroboratively support the intended nutritive effect of the substance under the conditions of its intended use.) In addition, for any animal feeding study a factor to be considered is whether data and information obtained from a feeding study conducted in one animal species (or in one stage of life of an animal species) can be used to support safety in another animal species (or in a different stage of life in the same animal species). See Response 145 for a discussion of when data and information that are obtained from an animal study and bear on the nutritive effect of a substance could be extrapolated from one animal species to another animal species, or to a different stage of life of the same animal species. In the following paragraphs, we provide examples of when data and information bearing on the nutritive effect of a substance intended for use in animal food could be established through the use of generally available and accepted data and information, or likely would need to be established through an animal feeding study that specifically supports the nutritive effect of the substance under the conditions of its intended use.

For some types of substances, generally available and accepted data and information about the function of a substance may be adequate to support the nutritive effect of the substance without also relying on an animal feeding study. For example, generally available and accepted data and information about the function of fat and carbohydrates as sources of dietary energy often can be used for substances providing fat intended as a source of dietary energy (rather than as a source of essential fatty acids) and for substances providing carbohydrates intended as a source of dietary energy. Likewise, generally available and accepted data and information about the nutritive content of human food can provide support for the nutritive effect of unsalable human food products (such as bruised produce) being collected for animal food use for their nutritional content rather than entering landfills or being incinerated.

For other types of substances, an animal feeding study (whether previously published or newly conducted) is the norm to support the nutritive effect of the substance. For example, for an ingredient that is intended to supply an essential mineral (such as phosphorus or zinc), generally available data and information can provide support that the mineral is an essential nutrient for the animal, but the bioavailability of the mineral in the ingredient that would be added to animal food generally needs to be determined in an animal feeding study conducted with that specific ingredient, because data regarding the amount of the mineral that is added to the feed in the ingredient (or that can be detected analytically in the feed or in the ingredient) would not provide evidence that the mineral is in a form that is available to the animal. However, for an ingredient that is intended to provide an essential amino acid, the need for an animal feeding study can depend on the form and composition of the ingredient. For example, it can be possible to rely on published literature to establish that a crystalline amino acid will be bioavailable to an animal (and, thus, functional). However, if a complex matrix, such as a biomass composed of microbial cells or a processed oilseed meal, is intended to be a source of amino acids, an animal feeding study generally would be needed to provide evidence that the bioavailability of the amino acids has not been adversely impacted by the other substances present in the complex matrix.

Technical effect in the food (rather than nutritive effect in the animal). As with a substance intended to provide a nutritive effect in the animal, data and information bearing on a substance's technical effect in the food (*e.g.,* substances such as anti-caking agents, binders, emulsifiers, enzymes, mixing aids, preservatives, processing aids, stabilizers, and substances added for aroma, flavor or other technical effects) may be necessary to demonstrate safety because of the physical form and properties of animal diets. Although generally available and accepted data and information can provide evidence of a technical effect in the food, it is common for studies to be conducted with the animal food to demonstrate the intended technical effect. Depending on the intended technical effect, an animal feeding study (whether previously published or newly conducted) may be also needed to demonstrate the intended technical effect of the substance. In the following paragraphs, we provide examples of when animal feeding studies may be needed to support the intended technical effect of the substance. We also provide examples of when an intended technical effect in animal food could be established through the use of generally available and accepted data and information about the technical effect and the studies conducted with the intended animal food matrix. As with a substance intended to provide a nutritive effect in the animal, when an appropriate study, which may be an animal feeding study, is already generally available (*e.g.,* in the peer-reviewed scientific literature), it can be possible to support the technical effect of a substance in the food without conducting a new study. If an appropriate study is not already generally available, a study conducted to support the technical effect in the food would ordinarily be published and, as discussed in Response 19, there would be a time gap between the publication of the study and the use of the published study to support a conclusion of GRAS status.

Enzymes are often added to animal food to alter the bioavailability of nutrients already in the food. For example, it is well known that the enzyme phytase increases the bioavailability to animals of the phosphorus present in grain (Ref. 53), and substances that provide phytase activity are often added to diets for poultry and swine. Poultry and swine diets are typically formulated with the minimal amount of phosphorus. If the phytase enzyme does not carry out the effect of improving phosphorus availability to the animal as intended, the consequence will be a diet that is deficient in phosphorus and therefore results in adverse impacts on animal health in the form of decreased growth, increased orthopedic disease (*e.g.,* rickets), and suffering animals (Ref. 54). As another example, protease enzymes can be added to an animal food to affect the digestibility of proteins in the food (Ref. 55). Both animal feeding studies and stability studies (to assess the stability of the enzyme in the food and, thus, its ability to perform its intended technical effect) are the norm when enzymes are added to animal food. However, when the function of an enzyme in animal food is well known, it is also common to use generally available and accepted data and information about the function of the enzyme in combination with animal feeding studies and stability studies to support the function of the enzyme (see section IV in CVM's experience document (Ref. 20)).

Substances such as binders, lubricants, and pelleting agents are added to animal food that will be fed as pellets. In some cases, such substances are added to ensure that the pellet retains its desired form and that the individual ingredients remain agglomerated, making it more difficult for an animal to select only those ingredients it prefers. In aquaculture foods, such substances are added to prevent the pellet from dissolving or prevent the nutrients from leaching out of the pellet. Depending on the circumstances, either technical effect studies conducted with the animal food, or generally available and accepted data and information about the function of the substance, can be used to support the intended technical effect, such as that of a binder, lubricant, or pelleting agent, etc., when added to animal food.

Flavors are added to animal food for certain species, generally for specific life stages of that species. For example, flavors can be added to animal food intended for consumption by piglets being transitioned from a milk-based diet to a commercial growth diet to increase consumption of the commercial growth diet. Flavors also are added to commercial animal food intended for aquaculture to attract newly hatched fish (fish fry) to the commercial food when the commercial food does not resemble the food that fish fry would consume in nature. If the fish fry are not attracted to the commercial food, the fish fry can starve to death. Animal feeding studies are the norm to support the function of the substance as a flavor when added to animal food.

Substances such as emulsifiers and stabilizers are added to animal food to ensure that an animal consumes all of the ingredients in the correct proportions in order to meet its nutritional needs. Inconsistent nutrient content and delivery of a diet to the animal can cause either nutrient deficiency diseases, or toxicities. For example, liquid cattle foods are often available to the animal at all times and cattle simply lick the feeding device to obtain the food. If the minerals present in the liquid fall out of suspension and settle to the bottom, the first animals to access the feeder will consume lower nutrient levels than expected, while those animals that access the feeder later and consume the bottommost material may be at risk of toxicity due to higher nutrient levels. For dry ingredients, the ingredients in the formulated diet must be uniformly dispersed and mixed, remain mixed during handling, and be physically stable as a formulated animal diet is moved through augers and conveyors, and transported in bulk in trucks, which can result in the loss of nutrients through sifting or "unmixing." These effects are assessed on the diet itself through appropriate studies.

(Comment 145) One comment asks us to accept reasonable arguments as to the worst-case exposures (inclusion levels) if the substance or class of substances has well-established use patterns rather than require utility data to support the intended nutritional effect. This comment also asks us to be flexible when utility data are warranted to support an entirely new use in animal feeds when utility data from one representative species would be sufficient to address utility in the target animal.

(Response 145) When animal feeding studies are necessary to provide data and information bearing on the nutritive effects of a substance intended for use in animal food, the potential to extrapolate from the conclusions of a feeding study conducted in one animal species to another animal species depends on the similarities of their digestive systems, physiology, and diets. For example, when a bioavailability study for selenium present in selenium yeast is conducted in cattle (which have a fermentative digestive tract), it can be possible to extrapolate the conclusions of that bioavailability study to other animal species that have fermentative digestive tracts. However, when a bioavailability study for copper is conducted in a ruminant animal species, it may not be appropriate to extrapolate the conclusions of that bioavailability study to sheep, even though sheep are ruminants, because sheep physiology is such that sheep are much more sensitive to copper toxicity than other ruminant species. In addition, when a bioavailability study for a nutrient is conducted in animals other than fish, it may not be possible to extrapolate the conclusions of that bioavailability study to aquaculture-fed fish, because aquaculture diets that are consumed in the water present special challenges, particularly for slow-feeding or bottom-feeding aquaculture species, where the diet pellet must retain its form and nutrient content until the pellet is consumed. For example, it is possible for nutrients that are soluble in water to dissolve out of the pellet before consumption, preventing the aquaculture animal from accessing all the required nutrients.

See Response 144 for a discussion of circumstances where generally available and accepted data and information can be used to provide evidence bearing on the nutritive effects of a substance intended for use in animal food (*e.g.,* for substances providing fat intended as a source of dietary energy, for substances providing carbohydrates intended as a source of dietary energy, for unsalable human food products, and when a crystalline amino acid is added to animal food). See also Response 150 for additional discussion of limitations on the use of generally available and accepted data and information, such as a weight of evidence approach, for the extrapolation of available data and information from an animal species other than the target animal.

Regardless of whether the intended use of the notified substance is to provide nutritive value or technical effect, any person who concludes that the available data and information regarding the safety of a notified substance under the conditions of its intended use satisfy GRAS criteria must have a basis for the conclusion of GRAS status, irrespective of whether that person notifies us of that conclusion in a GRAS notice. If you submit your conclusion of GRAS status to FDA, you must explain how the data and information in your GRAS notice provide the basis for your conclusion, *e.g.,* in Part 2 of the GRAS notice (where you would describe the applicable data and information), in the narrative in Part 6 of your GRAS notice, or in both Parts 2 and 6 of your GRAS notice. We would then evaluate whether the data, information, and narrative in your GRAS notice support your conclusion. When data and information bearing on the physical or other technical effect of the notified substance are necessary to support safety, we could conclude that a GRAS notice that does not discuss such data and information is incomplete, and either contact a notifier to request an amendment discussing such data and information, or issue an insufficient basis letter.

(Comment 146) One comment asserts that a requirement for proof of utility, with subsequent publication of utility data, is unnecessary, and that a requirement for utility data to be documented by means of a peer-reviewed publication would burden the industry with additional cost, not only to conduct the studies but also to prepare the manuscript and have it accepted for publication. This comment also asserts that finding a journal willing to publish such germane studies may be challenging because the manuscript may be viewed as serving the manufacturer's interest rather than providing any new scientific information. As alternatives to publication of a target animal feeding study, this comment suggests means such as documenting the chemical nature of the substance in relation to same (or similar) substance with ample public information, and placing unpublished studies conducted by the notifier in the context of published literature about the use of the substance or related substances. This comment also asserts that CVM and industry resources could be better utilized to demonstrate the safety of the intended use of the substance with a focus on establishing the worst-case exposure and relating it to available safety information to establish a margin of safety.

(Response 146) See Response 15, in which we respond to comments asserting it can be difficult to publish data and information that do not raise an issue of concern. Consistent with CFSAN's experience during the Interim Pilot program, we believe that some journals directed to food safety would be willing to publish data and information bearing on the physical or other technical effect the notified substance is intended to produce when those data and information are necessary to demonstrate safety (see section III.A.1 of CFSAN's 2010 experience document (Ref. 18)).

See also Response 144 for a discussion of circumstances where generally available and accepted data and information can be used to provide evidence bearing on the nutritive effects of a substance intended for use in animal food. There may be situations where sufficient generally available and accepted data and information on exposure to the substance or class of substances can satisfy GRAS criteria without publication of specific data and information bearing on the physical or other technical effect the notified substance is intended to produce. For example, as discussed in section IV of CVM's experience document during the Interim Pilot program CVM responded with a "no questions letter" when the use of published information for technical effects such as nutrient, enzyme, and component of a defoamer was used, in whole or in part, to support such technical effects (Ref. 20). As discussed in Response 12, GRAS status may be corroborated by unpublished scientific data, information, or methods, and there may be some unpublished scientific data, information, or methods regarding the safety of a use of a food substance. As discussed in Response 8, the criteria for GRAS status through scientific procedures provide for the application of "generally available and accepted" scientific data, information, or methods, which "ordinarily" are published and, thus, provide flexibility for supporting a conclusion of GRAS status through the application of scientific data, information, or methods that are generally available through a mechanism other than publication in a peer-reviewed scientific journal.

See the discussion in Response 150 regarding the evaluation of safety studies, including the applicability of worst-case exposure on a case-by-case basis.

F. Part 3 of a GRAS Notice for a Substance Intended for Use in Animal Food: Target Animal and Human Exposures (§ 570.235)

1. Substances Intended for Use in Food or Drinking Water for Animals

(Comment 147) Comments that address Issue 11c support clarifying that the GRAS notification procedure is applicable to substances used in both food and drinking water of animals.

(Response 147) The final requirements for Part 3 of a GRAS notice specify that "animal food" includes "drinking water." See also Response 142.

2. Data and Information About the Dietary Exposure for the Target Animal

(Comment 148) One comment states that exposure information can usually be obtained from published data sources and that if a worst-case exposure cannot be established without new data, then data for one representative animal species are sufficient, especially if the selected species represents a worst-case scenario. As an example, the comment suggests that data from one representative poultry species would be sufficient to address the conditions of use of a notified substance intended for poultry. As noted in Comment 142, another comment asks CVM to accept the anticipated consumption levels by animals that are based upon general formulation principles that consider the availability of contemporary feedstuffs.

(Response 148) See the regulatory text of § 570.235(a) for the requirements for what you must provide in Part 3 of a GRAS notice regarding exposure to the target animal. The regulatory text addressing the types of exposure to the target animal parallels the regulatory text for dietary exposure to a notified substance in the human food regulations (see § 170.235). As noted in Response 142, you may base the levels of use upon general formulation principles that consider the availability of contemporary feedstuffs. We agree that exposure information may be available from published data sources. If exposure cannot be established without new data, then data for one representative animal species may be sufficient if the selected species represents a worst-case scenario.

(Comment 149) One comment asks that any restatement of the regulatory text regarding dietary exposure consider how to use the word "consumer," because "consumers" are humans for the purpose of part 170 but are "animals" for the purpose of part 570.

(Response 149) To reduce the potential for confusion, the final requirements for part 3 of a GRAS notice for a substance intended for use in animal food do not use the term "consumer."

G. Data and Information in a GRAS Notice About Safety for the Target Animal (§ 570.250)

(Comment 150) Comments that address Issue 11e agree that data and information in a GRAS notice must be sufficient to address safety for the target animal. However, most of these comments express concern about the standard for demonstrating safety to the target animal, specifically whether safety must be established through feeding studies specific to the target animal or could be extrapolated from data and information regarding species other than the target animal. Although one comment asserts that a notifier must submit evidence that the substance is safe for all the species in question if a substance is expected to be consumed by different animal species, other comments emphasize that safety could be established through either feeding studies in the target animal or through extrapolation of data obtained from species other than the target animal. Some comments suggest that the rule require a clear and concise written explanation of how studies in non-target species relate to the target animal rather than require safety data in the target animal species.

One comment disagrees that the GRAS notification procedure should establish any absolute requirement for data addressing safety for the target species. This comment asserts that CVM should not require species-specific data for all substances and species covered by the intended use of the notified substance because recognized scientific procedures, such as a weight of evidence approach, allow for the extrapolation of data and that these types of scientific procedures can be applied to notified substances. This comment also asserts that a CVM requirement for safety data in the target animal, rather than a written explanation of how studies in non-target species relate to the target animal, cannot be scientifically justified and will put the animal feed industry at a disadvantage for obtaining recognition of new GRAS substances, and that the additional cost and time will stifle innovation and reduce growth in the U.S. feed industry and animal agriculture.

(Response 150) Whether species-specific data and information (such as feeding studies) are necessary to satisfy GRAS criteria depends on the intended use of the notified substance. We recognize that there may be situations where scientific procedures, such as a weight of evidence approach, allow for the extrapolation of available data and information from an animal species other than the target animal. For example, CVM had no questions regarding an enzyme preparation intended for use in food for turkeys, broiler chickens, and laying hens, when the feeding studies used to support target animal safety were conducted only on broiler chickens (Ref. 20). In such cases, you would explain the relevance of the available data to the target species in the narrative required in Part 6 of a GRAS notice rather than describe species-specific data and information.

However, extrapolating data from one animal species to another is not always appropriate because a substance that is safe for use in one animal species may not be safe for use in another species or in the same species at a different stage of life. For example, a substance that is safe for use in a species that is a ruminant animal (*e.g.,* cattle) may not be safe for use in a species considered a monogastric animal (*e.g.,* swine) because of the difference in their digestive systems and different nutrient requirements. For example, in ruminant animals, non-protein nitrogen compounds (*e.g.,* urea and biuret) release ammonia, which is then metabolized by rumen microorganisms into microbial proteins. These microbial proteins are a useful source of protein to ruminant animals. However, in monogastric animals, the liberated ammonia from non-protein nitrogen compounds is absorbed directly by the animal, resulting in adverse toxicological events, and possibly death. Even within the same species of animal, or for different species in the same class of animals (*e.g.,* chicken, duck, turkey), extrapolating safety data may not be appropriate. For example, a substance that is safe for laying hens may not be safe for use in broilers because of the different nutrient requirements, such as the higher calcium level in a laying hen diet (which is intended to meet the nutrient demand for egg production). If that high level of calcium is consumed by broiler chickens, the potential calcification of soft tissue such as that of kidneys could become detrimental to the broiler chickens. Likewise, a substance that is safe for chickens may not be safe for ducks or turkeys because the nutrient requirements for different species of poultry vary widely. Feeding a diet intended for one species of poultry to another species could cause nutrient imbalances, deficiencies, or excesses, which could have adverse consequences ranging from loss of production to damages to tissues and organs and even to death. When extrapolating data and information from another animal species is not appropriate, in Part 6 of your GRAS notice you would discuss data and information developed specifically for the target animal, or for the stage of life in the same animal species, rather than explain how you extrapolated available data and information from an animal species other than the target animal, or how you extrapolated available data and information from the same animal species to a different life stage of that animal species.

Any person who concludes that the available data and information regarding the safety of a notified substance under the conditions of its intended use satisfy GRAS criteria must have a basis for the conclusion of GRAS status, regardless of whether that person notifies us of that conclusion in a GRAS notice. A resource that may help determine when it could be appropriate to extrapolate species-specific data and information from one animal species to another animal species is our guidance entitled "Guidance for Industry: Recommendations for Preparation and Submission of Animal Food Additive Petitions" (# 221) (June 2015) (Ref. 56). Section G.2 of that guidance (on target animal safety) recommends that target animal safety studies be conducted using the life stage and animal species for which the food additive will be marketed. In cases where the food additive is intended for multiple animal species or life stages, the food additive should be tested in the most sensitive life stage and/or species. The guidance recommends using current scientific literature to identify the most sensitive life stage and/or species. As with guidance documents prepared by CFSAN, CVM's scientific recommendations in a guidance directed to food additives can be applied to the evaluation of whether a substance is GRAS under the conditions of its intended use (see Response 66).

Another resource is a book entitled "Safety of Dietary Supplements for Horses, Dogs, and Cats" by the National Research Council (Ref. 57), which identifies five factors to consider when selecting appropriate surrogates for horses, dogs and cats. In addition, it advises considering nutritional, metabolic, pharmacokinetic, and natural dietary patterns when selecting appropriate animal model species. Although the material is directed to only three target animals, some aspects of its approach can be generalized.

If you submit your conclusion of GRAS status to FDA, you must explain how the data and information in your GRAS notice provide the basis for your conclusion; we would then evaluate whether the data, information, and narrative in your GRAS notice support your conclusion.

H. Data and Information in a GRAS Notice About the Safety for Humans Consuming Human Food Derived From a Food-Producing Animal (§§ 570.235 and 570.250)

(Comment 151) Some comments support clarifying the rule to explicitly require the submission of information about safety for both the target animal and for humans consuming human food derived from food-producing animals. One comment states that the safety and wholesomeness of food given to animals that eventually end up in human food must be held to the same standard as for a substance intended for use in human food. Another comment asks us to specify that the submission of data and information about both target animal and human safety is required when such data and information are developed for food-producing animals.

One comment states that it is the responsibility of the notifier to determine the extent of the safety assessment of a substance intended for use in the food of a food-producing animal. This comment asserts that there is no need to set explicit standards for addressing both target animal and human food safety in applicable sections of the rule, because whether new data, such as tissue residue data, would be warranted would be determined through application of general scientific principles from the fields of animal nutrition and metabolism.

Another comment asserts that neither human feeding studies nor tissue residue accumulation data should be required when available scientific information can be used to draw conclusions using a weight of the evidence approach, as CFSAN does for human food substances. This comment asserts that CVM must clarify what data need to be provided regarding safety for humans consuming human food derived from food-producing animals before industry could agree to the requirement.

(Response 151) We are clarifying the requirement to address safety for humans consuming human food derived from food-producing animals in Parts 3 and 6 of a GRAS notice.

In the requirements for Part 3 of a GRAS notice for a substance intended for use in animal food, we have modified the title of the regulatory text to specify that Part 3 addresses exposures to both the target animal and to humans consuming human food derived from food-producing animals (see § 570.235). When the intended use of the notified substance is in food for food-producing animals, you must provide: (1) The potential quantities of any residues that humans may be exposed to in edible animal tissues; and (2) the data and information you rely on to establish the potential quantities of such residues (see § 570.235(b)). These requirements parallel the requirements for target animal exposure, but are directed to the quantity of potential residues of the notified substance, and of any other substance that is expected to be formed in or on the animal food because of the use of the notified substance, and those residues from any other substances present with the notified substance, whether naturally, due to its manufacture (*e.g.*, contaminants or by-products), or produced as a metabolite in edible animal tissues when the notified substance is consumed by a food-producing animal. It is well established that substances consumed by food-producing animals, and substances such as metabolites produced by a food-producing animal, can accumulate in edible animal tissues and have an adverse impact on public health. For example, aflatoxin M1 is a metabolite of aflatoxin B1 that is produced during normal biological processes of animals ingesting the toxin (*e.g.*, from food contaminated with aflatoxin B1) and has been shown to cause liver cancer in certain animals (Ref. 58). As another example, there can be human food safety concerns about the level of selenium in animal tissues when food-producing animals consume large amounts of a substance that contains selenium in their diets.

We agree that the specific data and information that are necessary to determine the safety for humans consuming human food derived from a food-producing animal would be determined through the application of general scientific principles from the fields of animal nutrition and metabolism and that it is the notifier's responsibility to determine what those specific data and information are. Therefore, we have modified the requirements for the narrative in Part 6 of a GRAS notice to clarify that the narrative must address the safety for both the target animal and for humans consuming human food derived from food-producing animals (see § 570.250(a)(1) and (b)).

I. Filing Decision, Opportunity for a Notifier To Submit an Amendment, and Asking Us To Cease To Evaluate a GRAS Notice for a Substance Intended for Use in Animal Food (§§ 570.260 and 570.265)

(Comment 152) Some comments express concern about differences in how CFSAN and CVM administered GRAS notices during the Interim Pilot program. Some comments describe CFSAN's practice of using conference calls to obtain a clarification or additional information, with a reasonable period of time for the notifier to provide the clarification or additional information. These comments assert that CVM's practice is different from CFSAN's practice because CVM does not contact a notifier to discuss CVM's questions after a submission has been accepted for filing. One comment asserts that CVM has informally indicated that once a GRAS notice is accepted for filing, there will be no further communication with the notifier and the GRAS notice will be judged solely on what was accepted for filing. This comment further asserts that such a process is unreasonable because the error or omission may be trivial and/or easily remedied. This comment also asserts that allowing informal contacts (including telephone, email, and fax) to address minor issues would be consistent with how FDA has handled a wide range of submissions that require review. Another comment asserts that CVM's practice of not contacting the notifier is a major concern for the industry and that CVM's reviewers may have questions that could be easily answered by the notifier, if contacted.

Some comments ask CVM to engage in the same informal practice as CFSAN, with respect to contacting the notifier and allowing remedial action, if such action may be completed in a reasonable period of time. Some comments ask the Centers to establish a uniform system of contact and communication after a submission (and/or agreeing to evaluate an amendment to a GRAS notice) to prevent delays or other inefficiencies over issues that could easily be clarified and resolved. Some comments note that uniformity between CFSAN and CVM in the submission and handling of requests to cease to evaluate a GRAS notice is of great importance in maintaining transparency and efficiency in the GRAS notification procedure.

(Response 152) The regulatory text governing what CVM will do with a GRAS notice (§ 570.265) is the same as the regulatory text governing what CFSAN will do with a GRAS notice (§ 170.265). In addition, the regulatory text that provides for a notifier who submits a GRAS notice to CVM to submit a timely amendment to a filed GRAS notice, and to ask us to cease to evaluate a GRAS notice (§ 570.260), is the same as the regulatory text that provides for a notifier who submits a GRAS notice to CFSAN to submit a timely amendment to a filed GRAS notice, and to ask us to cease to evaluate a GRAS notice (§ 170.260).

We disagree that CVM did not contact notifiers during the Interim Pilot program. As shown in table 1 in CVM's experience document (Ref. 20), CVM contacted the notifier regarding 9 of 18 GRAS notices during its evaluation process. CVM issued "no questions letters" to seven of these nine notices after the notifiers provided clarifying amendments.

Moving forward under the final rule, CVM intends to consider the same factors that CFSAN considers regarding whether to file a submission as a GRAS notice (see Response 85), the purpose of contacting a notifier (including whether to provide an opportunity for a notifier to ask us to cease to evaluate a GRAS notice) (see Response 80), and the transparency of the reasons for a "cease to evaluate letter" (see Response 81). Because our factors regarding the purpose of contacting a notifier, and the provisions that provide an opportunity for a notifier to submit an amendment, consider whether an amendment is (or could be) timely, the final rule does, as requested by the comments, consider whether an amendment could be prepared and submitted in a reasonable period of time. Importantly, as discussed in Response 101, the role of an amendment is to clarify questions that we have about your conclusion of GRAS status, rather than to substantively amend the notice. Whether we will evaluate an amendment to a GRAS notice before responding to the notice is a matter that we will consider on a case-by-case basis.

J. Opportunity for a Notifier To Submit a Supplement to a GRAS Notice for a Substance Intended for Use in Animal Food (§ 570.280)

(Comment 153) One comment asks CVM to adopt CFSAN's approach of allowing a notifier to submit information to a GRAS notice after FDA responds to the notice.

(Response 153) The rule provides that, if circumstances warrant, a notifier who submits a GRAS notice to CVM may submit a supplement to a filed GRAS notice after we respond to your notice by letter or cease to evaluate your notice (§ 570.280). As discussed in section VI of CVM's experience document (Ref. 20), as of December 31, 2015, CVM had not received any supplements to a GRAS notice.

K. GRAS Affirmation Petitions for Substances Used in Animal Food

CVM has no pending GRAS affirmation petitions and, thus, the final animal food regulations do not include provisions for the disposition of pending GRAS affirmation petitions for substances used in animal food.

XXVI. Editorial, Clarifying, and Conforming Amendments

The revised regulatory text includes several changes that we have made to make the requirements more clear and improve readability. The revised regulatory text also includes several conforming changes that we have made when a change to one provision affects other provisions. We summarize the principal editorial and conforming changes in table 29.

TABLE 29—PRINCIPAL EDITORIAL, CLARIFYING, AND CONFORMING CHANGES

Designation in the regulatory text (§)	Revision	Explanation
§ 20.100(c)(46)	Add new paragraph (c)(46) to clarify applicability of § 20.100 (the handling of FDA records upon a request for public disclosure) to GRAS notices in §§ 170.36(h) and 570.36(h).	Conforming change in light of the new GRAS notification procedures established in §§ 170.36 and 570.36.
§ 25.20(k)	• Replace "Affirmation of a food substance as GRAS for humans or animals, on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter" with "Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter". • Replace "unless categorically excluded in § 25.32(f), (k), or (r)" with "unless categorically excluded in § 25.32(f), (i), (j), (k), or (r)".	• Conforming change in light of the deletion of the GRAS affirmation petition process. • Correct the list of applicable categorical exclusions that apply to include the categorical exclusions listed in § 25.32(i) and (j).
§ 25.32(f)	Replace "Affirmation of a food substance as GRAS for humans or animals on FDA's initiative or in response to a petition, under parts 182, 184, 186, or 582 of this chapter" with "Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter".	• Clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself. • Conforming change in light of the deletion of the GRAS affirmation petition process.
§ 25.32 (i), (j), (k), and (r)	Replace "or GRAS affirmation petition" with "establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter".	• Clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself. • Conforming change in light of the deletion of the GRAS affirmation petition process.
§ 170.3(h), § 570.3(h)	• Specify "data from human, animal, analytical, or other scientific studies" rather than "data from human, animal, analytical, and other scientific studies". • Replace "appropriate to establish the safety of a substance" with "appropriate to establish the safety of a substance under the conditions of its intended use".	• Clarify that the four listed types of studies (human, animal, analytical, and other) do not necessarily apply in all circumstances. • Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS status applies to the intended conditions of use of a substance, not the substance itself.

TABLE 29—PRINCIPAL EDITORIAL, CLARIFYING, AND CONFORMING CHANGES—Continued

Designation in the regulatory text (§)	Revision	Explanation
170.3(i)	In the definition of "safe" or "safety," replace "under the intended conditions of use" with "under the conditions of its intended use".	Conforming change to consistently use the exact statutory language in section 201(s) "under the conditions of its intended use" rather than variations (such as under the intended conditions of use).
§ 170.3(k)	Replace "General recognition of safety shall be determined in accordance with 170.30" with "General recognition of safety shall be in accordance with § 170.30".	Conforming change. See Response 41.
Throughout § 170.30	Replace "§ 186.1" with "part 186"	Correction to clarify that the provision applies to all of part 186, not just § 186.1.
§ 170.30(a)	Replace the proposed regulatory text "there is reasonable certainty that the substance is not harmful under the intended conditions of use" with "there is reasonable certainty that the substance is not harmful under the conditions of its intended use".	Conforming change to consistently use the exact statutory language in section 201(s) "under the conditions of its intended use" rather than variations (such as under the intended conditions of use).
§ 170.30(b), § 570.30(b)	Replace "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive regulation for the ingredient" with "General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive".	• Clarify that FDA approves a food additive, not a "food additive regulation". • Clarify that the same quantity and quality of scientific evidence is required regardless of whether the substance is intended for use as an "ingredient".
§ 170.30(c)(1), § 570.30(c)(1)	Replace "General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation" with "General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive".	• Conforming change. See Response 41. • Clarify that FDA approves a food additive, not a "food additive regulation".
§ 170.30(c)(2)	• Replace "if the information about the experience establishes that the use of the substance is safe within the meaning of the act (see § 170.3(i))" with "if the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also § 170.3(i))". • Replace "in this country" with "in the United States"	• Conforming change to consistently use the exact statutory language in section 201(s) "under the conditions of its intended use" rather than variations (such as "the use of the substance"). • Clarify that the applicable section of the FD&C Act is section 201(u). Section 170.3(i) is in our regulations, not in the FD&C Act. • Editorial change to include the full name of the statute. • Editorial change to be specific that "this country" means "the United States".
170.30(c)(2), 170.38(a), 570.38(a).	Replace "the act" with "the Federal Food, Drug, and Cosmetic Act" in any provision that we otherwise revised.	Editorial. It is now our practice to include the full name of this statute when we refer to it.
§ 170.30(e)	• Replace "Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food on the determination that they are GRAS or subject to a prior sanction" with "Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food based on the view that they are GRAS under the conditions of their intended use or subject to a prior sanction". • Replace "All determinations of GRAS status or food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in part 184 or § 186.1 of this chapter" with "All affirmations of GRAS status or determinations of food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in part 184 or part 186 of this chapter".	• See Response 41. • Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS status applies to the intended conditions of use of a substance, not the substance itself. • Clarify that GRAS status pursuant to parts 184 and 186 is affirmed by FDA.

Table 29—Principal Editorial, Clarifying, and Conforming Changes—Continued

Designation in the regulatory text (§)	Revision	Explanation
§ 170.30(l)	Replace “Any change in part 182, part 184, or § 186.1 of this chapter shall be accomplished pursuant to § 170.38” with “Any change to the GRAS status of a food ingredient in part 182, part 184, or part 186 of this chapter shall be accomplished pursuant to § 170.38”.	Clarify the applicability of the requirement.
§ 170.35(a), § 570.35(a)	Replace “may affirm the GRAS status of substances” with “may affirm that a substance that directly or indirectly becomes a component of food is GRAS under the conditions of its intended use”.	• Editorial change to use the singular. • Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself.
§ 170.35(b)(1), § 570.35(b)(1).	Replace “If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS” with “If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS under the conditions of its intended use”.	Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself.
§ 170.35(b)(3), § 570.35(b)(3).	• Replace “convincing evidence that the substance is GRAS” with “convincing evidence that the substance is GRAS under the conditions of its intended use”. • Replace “listing the substance as GRAS in part 182, part 184, or part 186 of this chapter” with “listing the GRAS conditions of use of the substance in part 184 or part 186 of this chapter”.	• Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself. • Deleted reference to parts 182 and 582. If FDA affirms GRAS status, the affirmation regulation would appear in part 184 or 186.
§ 170.35(b)(4), § 570.35(b)(4).	Replace “there is a lack of convincing evidence that the substance is GRAS” with “there is a lack of convincing evidence that the substance is GRAS under the conditions of its intended use”.	Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself.
§ 170.38(a), § 570.38(a)	• Replace “may, in accordance with § 170.35(b)(4) or (c)(5), publish a notice in the **Federal Register** determining that a substance is not GRAS” with “may, in accordance with § 170.35(b)(4), publish a notice in the **Federal Register** determining that a substance is not GRAS under the conditions of its intended use”. • Replace “may, in accordance with § 570.35(b)(4) or (c)(5), publish a notice in the **Federal Register** determining that a substance is not GRAS” with “may, in accordance with § 570.35(b)(4), publish a notice in the **Federal Register** determining that a substance is not GRAS under the conditions of its intended use”.	• See Response 41. • Conforming change in light of the deletion of the GRAS affirmation petition process. • Include statutory language from section 201(s) of the FD&C Act to clarify that GRAS affirmation applies to the intended conditions of use of a substance, not the substance itself.
• Throughout part 170, subpart E. • Throughout part 570, subpart E.	Replace variations of “data or other information” with “data and information”.	Editorial change. Although data is a type of “information,” it is simpler and clearer to say “data and information.”
• Throughout part 170, subpart E. • Throughout part 570, subpart E.	Replace variations of “determine” and “determination” with “conclude” and “conclusion”.	See Response 41.
• Throughout part 170, subpart E. • Throughout part 570, subpart E.	• Replace “exempt” with “not subject to: • Replace “claim” with “view”	See Response 42.
§ 170.203, § 570.203	In the definition of “notifier,” add a parenthetical with examples of what we mean by “person” (*e.g.,* an individual, partnership, corporation, association, or other legal entity).	Clarification by including text from the definition of “person” in § 10.3.
§ 170.225(c)(4)	Replace the proposed phrase “applicable conditions of use” with “intended conditions of use”.	Clarifying change to use the statutory term “intended” in place of “applicable”.
§ 184.1(a)	Replace “The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS) for the purposes and conditions prescribed” with “The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and affirmed to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed”.	Clarify that the GRAS status of the uses of substances listed in part 184 has been affirmed by FDA, either on FDA’s initiative or in response to a GRAS affirmation petition.

TABLE 29—PRINCIPAL EDITORIAL, CLARIFYING, AND CONFORMING CHANGES—Continued

Designation in the regulatory text (§)	Revision	Explanation
§ 184.1(b)(1)	• Replace "shall independently establish" with "shall have a basis to conclude". • Remove the last sentence, *i.e.*, "Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with 170.35 of this chapter.".	• Conforming change to reflect "conclusions" of GRAS status. • Conforming change in light of the deletion of the GRAS affirmation petition process.
§ 186.1(a)	Replace "The indirect human food ingredients listed in this part have been reviewed by the Food and Drug Administration and determined to be generally recognized as safe (GRAS)" with "The indirect human food ingredients listed in this part have been reviewed by the Food and Drug Administration and affirmed to be generally recognized as safe (GRAS)".	Clarify that the GRAS status of the uses of substances listed in part 186 has been affirmed by FDA, either on FDA's initiative or in response to a GRAS affirmation petition.
§ 186.1(b)(1)	• Replace "shall independently establish" with "shall have a basis to conclude". • Remove the last sentence, *i.e.*, "Persons seeking FDA approval of an independent determination that a use of an ingredient is GRAS may submit a GRAS petition in accordance with 170.35 of this chapter.".	Conforming change in light of the deletion of the GRAS affirmation petition process.
§ 570.3(f)	• Add "of the species to which the substance is intended to be fed" in describing the animals consuming the substance. • Delete "in the United States" • Add "(and, for food-producing animals fed with such substance, also means a substantial history of consumption by humans consuming human foods derived from those food-producing animals) prior to January 1, 1958.	Changes to • Conform with revisions to § 570.30(a) and (c) • Conform with the corresponding definition for human food in § 170.3(f), which does not specify "in the United States." • Clarify that substantial history of consumption should be demonstrated by the same animal species as the species intended to be fed to conform with the submission requirements in part 5 of a GRAS notice when the basis for the conclusion of GRAS status is through experience based on common use in food (§ 570.245). • Clarify that substantial history of consumption for food-producing animals also should be demonstrated by a substantial history of consumption by humans consuming human foods derived from those food-producing animals prior to January 1, 1958 to conform with the submission requirements in part 5 of a GRAS notice.
§ 570.3(k)	Replace "General recognition of safety shall be determined in accordance with § 570.30" with "General recognition of safety shall be in accordance with § 570.30".	Conforming change. The GRAS notification procedure does not use the term "determine."
§ 570.3	Define "food-producing animal" to mean an animal used to produce human food.	Clarify the meaning of this term for the purpose of part 570, subpart E in light of provisions that address the safety of a substance for humans consuming human food derived from an animal used to produce human food.
§ 570.30(c)	Replace "General recognition of safety through experience based on common use in food prior to January 1, 1958, may be determined without the quantity or quality of scientific procedures required for approval of a food additive regulation" with "General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive".	• Conforming change. The GRAS notification procedure does not use the term "determine." • Clarify that FDA approves a food additive, not a "food additive regulation".
§ 570.30(d)	• Replace "ingredients listed as GRAS in part 582 of this chapter" with "ingredients listed as GRAS in part 582 of this chapter or affirmed as GRAS in part 584 of this chapter". • Replace "without specific inclusion in part 582 of this chapter" with "without specific inclusion in part 582 or part 584 of this chapter".	Clarify that the provisions apply regardless of whether an ingredient is listed as GRAS in part 582 or affirmed as GRAS in part 584.
§ 570.30(i)	Replace "Any use of such and ingredient" with "Any use of such an ingredient".	Editorial correction of "and" to "an".
570.225(c)(4), 570.225(c)(5), 570.230(c), 570.235, 570.240, 570.245.	Replace "food" with "animal food"	Clarification for part 570.

XXVII. Economic Analysis of Impacts

We have examined the impacts of the final rule under Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4). Executive Orders 12866 and 13563 direct us to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). We have developed a comprehensive Economic Analysis of Impacts that assesses the impacts of the final rule. We believe that this final rule is not a significant regulatory action as defined by Executive Order 12866.

The Regulatory Flexibility Act requires us to analyze regulatory options that would minimize any significant impact of a rule on small entities. The final rule replaces the voluntary GRAS affirmation petition process with a voluntary GRAS notification procedure. Similar to the petition process, we expect that profit-maximizing firms will only submit the GRAS notice when the private benefits equal or exceed the costs of the GRAS notice, regardless of the size of the firm. Because small firms face the same voluntary business decision as large firms, we certify that the final rule will not have a significant economic impact on a substantial number of small entities.

The Unfunded Mandates Reform Act of 1995 (section 202(a)) requires us to prepare a written statement, which includes an assessment of anticipated costs and benefits, before issuing "any rule that includes any Federal mandate that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more (adjusted annually for inflation) in any one year." The current threshold after adjustment for inflation is $146 million, using the most current (2015) Implicit Price Deflator for the Gross Domestic Product. This final rule will not result in an expenditure in any year that meets or exceeds this amount.

The final rule will eliminate the petition process to affirm a substance is GRAS and replace the petition process with a GRAS notification procedure. The level of effort required by a firm to reach a conclusion that a substance is GRAS for its intended use remains unchanged by the final rule. However, the rule will require that firms submit some additional information to support their conclusion with their notices. Although uncertain, we estimate that notifiers will spend between 5 more hours and 20 more hours to prepare and submit each notice. We estimate that this will cost notifiers less than $0.1 million each year.

For all affected notifiers, we expect that they will spend time reading and understanding the requirements of the final rule and revising standard operating procedures for preparing and submitting GRAS notices. We estimate that it will take from 20 hours to 80 hours for notifiers to perform this action. Firms with outstanding GRAS affirmation petitions may choose to submit GRAS notices and incorporate the information included in their petition. To account for the additional effort by these firms, we include the one-time cost to prepare and submit a GRAS notice for all outstanding petitions. We estimate that notifiers will spend between 170 and 190 hours to submit GRAS notices for each outstanding petition. The total one-time costs of the final rule range from $0.8 million to $2.7 million.

We estimate that over 10 years with a 7 percent discount rate, the present value of the total costs of the final rule range from $0.9 million to $3.3 million; with a 3 percent discount rate, the present value of the total costs range from $0.9 million to $3.4 million. The annualized costs of the rule range from $0.1 million to $0.4 million with a 7 percent discount rate and range from $0.1 million to $0.5 million with a 3 percent discount rate.

We do not quantify the benefits of the final rule. However, based on the differences in review time between the GRAS petition process and the GRAS notification procedure, we anticipate that industry will benefit from the more speedy notification procedure. For example, we have filed more than 600 GRAS notices for human food substances since 1998. During this time, it took an average of 200 days for us to respond to 588 GRAS notices; it took an average of 7.9 years to complete 24 previous GRAS affirmation petitions. We began to accept GRAS notices for animal food substances in 2010 and we have filed 18 GRAS notices for animal food substances since that time. It took an average of 294 days for us to respond to 12 GRAS notices with a "no questions letter" or "insufficient basis letter"; it took an average of 4.9 years to respond to the three previous GRAS affirmation petitions. With the GRAS notification procedure, we can complete our evaluation within the timelines specified in the final rule.

The Economic Analysis of Impacts of the final rule performed in accordance with Executive Order 12866, Executive Order 13563, the Regulatory Flexibility Act, and the Unfunded Mandates Reform Act (Ref. 51) is available at *http://www.regulations.gov* under the docket number for this final rule and at *http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/EconomicAnalyses/default.htm.*

XXVIII. Analysis of Environmental Impact

We have carefully considered the potential environmental effects of this action. We have concluded under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

XXIX. Paperwork Reduction Act of 1995

This final rule contains information collection provisions that are subject to review by OMB under the PRA (44 U.S.C. 3501–3520). The title, description, and respondent description of the information collection provisions are shown in the following paragraphs with an estimate of the one-time and annual reporting burdens. Included in the estimate is the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing each collection of information.

Title: Substances Generally Recognized as Safe Notification Procedure (21 CFR parts 170 and 570) (OMB Control No. 0910–0342)—Revision.

Description: The FD&C Act requires that all food additives (as defined by section 201(s)) be approved by FDA before they are marketed (sections 402(a)(2)(C) and 409 of the FD&C Act). Section 201(s) of the FD&C Act excludes from the definition of a food additive a substance "generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use." This final rule amends our regulations in parts 170 and 570 and revises the information collection provisions regarding the notification procedures for GRAS substances. The regulations implement the GRAS provision of section 201(s) of the FD&C Act in part 170 and part 570 for human food and animal food, respectively.

Description of Respondents: Respondents to the collection of information are manufacturers of substances used in human food and animal food. We estimate there are 480 such respondents. As estimated in the Final Regulatory Impact Analysis (Ref. 51), approximately 340 to 460 notifiers (for human food) and approximately 10 to 20 notifiers (for animal food) will be affected by the final rule. The Final Regulatory Impact Analysis reflects an overall increase in respondents to the program and we have therefore adjusted our respondent numbers accordingly.

As discussed in section II.B of the preamble to this final rule, previously manufacturers were invited to submit notices of their independent GRAS determinations for review under the framework of the proposed rule during the period between issuance of the proposed rule and any final rule based on the proposed rule. The proposed regulations provided a standard format for the voluntary submission of a notice. To date, the GRAS program has been administered under these proposed procedures. Comments regarding the information collection topics solicited in the proposed rule and subsequent 2010 notice are discussed in the preamble in sections IV, VII, and X through XVIII. While none of the comments suggested we modify the estimated annual burden associated with the information collection, we have revised the underlying notification procedures and, consequently, have revised the underlying information collection provisions consistent with the final rule.

Specifically the final rule establishes a voluntary administrative procedure for notifying FDA about a conclusion that a substance is GRAS under the conditions of its intended use in human food or animal food. The final rule explains that a GRAS notice must include the following seven parts:

TABLE 30—INFORMATION TO BE INCLUDED IN EACH PART OF A GRAS NOTICE

Part No.	Information to be included
Part 1	Signed statements and a certification.
Part 2	The identity, method of manufacture, specifications, and physical or technical effect of the notified substance.
Part 3	Dietary exposure to the notified substance.
Part 4	Self-limiting levels of use in circumstances where the amount of the notified substance that can be added to human food or animal food is limited because the food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical.
Part 5	The history of consumption of the substance for food use by a significant number of consumers (or animals in the case of animal food) prior to January 1, 1958, if a conclusion of GRAS status is based on common use of the substance in food prior to 1958.
Part 6	A narrative that provides the basis for the notifier's conclusion of GRAS status, including why the scientific data, information, methods, and principles described in the notice provide a basis for the conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use.
Part 7	A list of the generally available data, information, and methods the notifier cites in the GRAS notice.

The information submitted to us in a GRAS notice is necessary to allow us to administer efficiently the FD&C Act's various provisions that apply to the use of substances added to food, specifically with regard to whether a substance is GRAS under the conditions of its intended use or is a food additive subject to premarket review. We will use the information collected through the GRAS notification procedure to complete our evaluation within the timelines specified in the final rule.

One-Time Reporting Burden

Table 31 shows the estimated one-time reporting burden associated with the final rule. We expect that all respondents to the information collection will spend time reading and understanding the requirements of the final rule and revising standard operating procedures for preparing and submitting GRAS notices. As noted, we estimate that approximately 340 to 460 notifiers (for human food) and approximately 10 to 20 notifiers (for animal food) will be affected by the final rule. We use the upper-bound estimates of 460 and 20 respondents as shown in rows 1 and 2. We estimate that it will take from 20 to 80 hours for respondents to perform this action. We use the upper-bound estimate of 80 hours as shown in rows 1 and 2. Of the 480 affected respondents, some will have outstanding GRAS petitions. Firms with outstanding GRAS petitions regarding substances intended for use in human food may choose to submit GRAS notices and incorporate the information included in their petition. As estimated in the Final Regulatory Impact Analysis (Ref. 51), up to 45 petitions (for human food) will be submitted as GRAS notices and incorporated. We use the upper-bound estimate of 45 as shown in row 3. To account for the additional effort by these firms, we include the one-time burden to prepare and submit a GRAS notice for all outstanding petitions. Because there are no outstanding GRAS petitions regarding substances intended for use in animal food, we do not account for any burden for the submission of a GRAS notice that incorporates a GRAS petition regarding a substance intended for use in animal food. We estimate that respondents will spend between 170 and 190 hours to submit GRAS notices for each outstanding petition and have used, therefore, an average estimate of 185 hours as shown in row 3.

TABLE 31—ESTIMATED ONE-TIME REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Notifier's review of final rule and revision of procedures for preparing and submitting GRAS notices for human food, 170.210 through 170.270.	460	1	460	80	36,800
Notifier's review of final rule and revision of procedures for preparing and submitting GRAS notices for animal food, 570.210 through 570.270	20	1	20	80	1,600
Prepare and submit GRAS notice for an outstanding GRAS petition, 170.285	45	1	45	185	8,325
Total					46,725

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recurring Reporting Burden

Table 32 shows the estimated recurring annual reporting burden associated with the final rule. As previously discussed, the final rule replaces the petition process with a GRAS notification procedure. The level of effort required by a firm to reach a conclusion that a substance is GRAS for its intended use remains unchanged by the final rule. However, the final rule requires that firms submit some additional information to support the conclusions found within their notices. The additional information might include an amendment (§§ 170.260 and 570.260); a supplement (§§ 170.280 and 570.280); a request for FDA to cease to evaluate a GRAS notice (§§ 170.260 and 570.260); an incorporation into a GRAS notice (§§ 170.215 and 570.215); and, information required when the intended conditions of use of a notified substance includes use in a product subject to regulation by FSIS, including authorization to us to share any trade secrets with FSIS (§ 170.270). Because the amount of additional information may vary, we estimate that respondents will spend between 155 and 170 hours to prepare and submit each notice. Using the upper-bound figure of 170 hours, we therefore estimate that the 50 notifiers for human food and 25 notifiers for animal food will expend 12,750 hours annually as shown, respectively, in rows 1 and 2.

TABLE 32—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
GRAS notification procedure for human food, 170.210 through 170.270	50	1	50	170	8,500
GRAS notification procedure for animal food, 570.210 through 570.270	25	1	25	170	4,250
Total					12,750

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Recordkeeping

The final rule does not contain recordkeeping requirements. We believe that documentation used by respondents in support of a conclusion of GRAS status is information that is collected and retained as a part of usual and customary business practices for a firm engaged in the manufacture of substances used in human food and animal food. We have, therefore, not provided an estimate for these activities (5 CFR 1320.3(b)(2)).

This final rule also refers to other currently approved collections of information found in our regulations. These collections of information are subject to review by OMB under the PRA. The collections of information in 21 CFR 25.32(i) are approved under OMB control number 0910–0541. The collections of information in 21 CFR 10.33 are approved under OMB control number 0910–0191.

The information collection provisions of this final rule have been submitted to OMB for review as required by section 3507(d) of the PRA. Before the effective date of this final rule, FDA will publish a notice in the **Federal Register** announcing OMB's decision to approve, modify, or disapprove the information collection provisions in this final rule. An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

XXX. Federalism

We have analyzed this final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

XXXI. References

The following references are on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they also are available electronically at *http://*

www.regulations.gov. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register,** but Web sites are subject to change over time.

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4. United States Government Accountability Office, "Report to Congressional Requestors on Food Safety: FDA Should Strengthen Its Oversight of Food Ingredients Determined to Be Generally Recognized as Safe (GRAS)," Report No. GAO–10–246, (*http://www.gao.gov/new.items/d10246.pdf*), February 2010. Accessed and printed on May 3, 2010. See Reference 2 to the 2010 notice.
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10. Letter dated November 17, 2010, from Joann M. Givens of FDA to Mr. Tim Baggs, Charge Beverages Corporation, (*http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm233990.htm*). Accessed and printed on January 31, 2016.
11. Letter dated November 17, 2010, from Joann M. Givens of FDA to Rhonda Kallman of New Century Brewing Company, (*http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm234028.htm*). Accessed and printed on January 31, 2016.
12. Letter dated November 17, 2010, from Joann M. Givens of FDA to Jaisen Freeman, Chris Hunter, and Jeff Wright of Phusion Projects, (*http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm234023.htm*). Accessed and printed on January 31, 2016.
13. Letter dated November 17, 2010, from Joann M. Givens of FDA to Michael Michail of United Brands Company, (*http://www.fda.gov/iceci/enforcementactions/warningletters/2010/ucm234002.htm*). Accessed and printed on January 31, 2016.
14. TTB, Industry Circular 2010–8, (*http://www.ttb.gov/industry_circulars/archives/2010/10–08.html*), 2010. Accessed and printed on January 21, 2016.
15. The National Academies of Sciences, Health and Medicine Division, "Caffeine in Food and Dietary Supplements: Examining Safety—Workshop Summary," (*http://www.nationalacademies.org/hmd/Reports/2014/Caffeine-in-Food-and-Dietary-Supplements-Examining-Safety.aspx*), 2014. Accessed and printed on May 27, 2016.
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19. "Substances that Are Generally Recognized as Safe (GRAS); Updated Experience With GRAS Notices," Memorandum Dated June 1, 2016, from Paulette M. Gaynor of FDA to Docket No. FDA–1997–N–0020.
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List of Subjects

21 CFR Part 20

Confidential business information, Courts, Freedom of information, Government employees.

21 CFR Part 25

Environmental impact statements, Foreign relations, Reporting and recordkeeping requirements.

21 CFR Part 170

Administrative practice and procedure, Food additives, Reporting and recordkeeping requirements.

21 CFR Part 184

Food additives.

21 CFR Part 186

Food additives, Food packaging.

21 CFR Part 570

Animal feeds, Animal foods, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR chapter I is amended as follows:

PART 20—PUBLIC INFORMATION

■ 1. The authority citation for part 20 continues to read as follows:

Authority: 5 U.S.C. 552; 18 U.S.C. 1905; 19 U.S.C. 2531–2582; 21 U.S.C. 321–393, 1401–1403; 42 U.S.C. 241, 242, 242a, 242l, 242n, 243, 262, 263, 263b–263n, 264, 265, 300u–300u–5, 300aa–1.

■ 2. In § 20.100, add paragraph (c)(46) to read as follows:

§ 20.100 Applicability; cross-reference to other regulations.

* * * * *

(c) * * *

(46) Generally recognized as safe (GRAS) notices, in part 170, subpart E and part 570, subpart E of this chapter.

PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

■ 3. The authority citation for part 25 continues to read as follows:

Authority: 21 U.S.C. 321–393; 42 U.S.C. 262, 263b–264; 42 U.S.C. 4321, 4332; 40 CFR parts 1500–1508; E.O. 11514, 35 FR 4247, 3 CFR, 1971 Comp., p. 531–533 as amended by E.O. 11991, 42 FR 26967, 3 CFR, 1978 Comp., p. 123–124 and E.O. 12114, 44 FR 1957, 3 CFR, 1980 Comp., p. 356–360.

■ 4. In § 25.20, revise paragraph (k) to read as follows:

§ 25.20 Actions requiring preparation of an environmental assessment.

* * * * *

(k) Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, unless categorically excluded in § 25.32(f), (i), (j), (k), or (r).

* * * * *

■ 5. In § 25.32, revise paragraphs (f), (i), (j), (k), and (r) to read as follows:

§ 25.32 Foods, food additives, and color additives.

* * * * *

(f) Establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, and establishment or amendment of a regulation for a prior-sanctioned food ingredient, as defined in §§ 170.3(l) and 181.5(a) of this chapter, if the substance or food ingredient is already marketed in the United States for the proposed use.

* * * * *

(i) Approval of a food additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is present in finished food-packaging material at not greater than 5 percent-by-weight and is expected to remain with finished food-packaging material through use by consumers or when the substance is a component of a coating of a finished food-packaging material.

(j) Approval of a food additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, the granting of a request for exemption from regulation as a food additive under § 170.39 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, when the substance is to be used as a component of a food-contact surface of permanent or semipermanent equipment or of another food-contact article intended for repeated use.

(k) Approval of a food additive petition or color additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective, for substances added directly to food that are intended to remain in food through ingestion by consumers and that are not intended to replace macronutrients in food.

* * * * *

(r) Approval of a food additive petition or color additive petition, establishment or amendment of a regulation for a food substance as GRAS under the conditions of its intended use for humans or animals under parts 182, 184, 186, 582, or 584 of this chapter, or allowing a notification submitted under 21 U.S.C. 348(h) to become effective for a substance that occurs naturally in the environment, when the action does not alter significantly the concentration or distribution of the substance, its metabolites, or degradation products in the environment.

PART 170—FOOD ADDITIVES

■ 6. The authority citation for part 170 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

■ 7. In § 170.3, revise paragraph (h), the first sentence of paragraph (i), and paragraph (k), to read as follows:

§ 170.3 Definitions.

* * * * *

(h) *Scientific procedures* include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. * * *

* * * * *

(k) *General recognition of safety* shall be in accordance with § 170.30.

* * * * *

■ 8. Amend § 170.30 as follows:

■ a. Revise the last sentence of paragraph (a);

■ b. Revise paragraph (b).

■ c. Revise the the first sentence of paragraph (c)(1) and revise paragraph (c)(2);

■ d. Remove "§ 186.1" and add in its place "part 186" wherever it appears in paragraph (d);

■ e. Revise paragraph (e);

■ f. Remove and reserve paragraph (f);

■ g. Remove "§ 186.1" and add in its place "part 186" in paragraphs (h) introductory text, (h)(1), (i), (j), and (k); and

■ h. Revise the last sentence of paragraph (l).

The revisions read as follows:

§ 170.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) * * * General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful under the conditions of its intended use (see § 170.3(i)).

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. * * *

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if

the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also § 170.3(i)). Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

* * * * *

(e) Food ingredients were listed as GRAS in part 182 of this chapter during 1958–1962 without a detailed scientific review of all available data and information relating to their safety. Beginning in 1969, the Food and Drug Administration has undertaken a systematic review of the status of all ingredients used in food based on the view that they are GRAS under the conditions of their intended use or subject to a prior sanction. All affirmations of GRAS status or determinations of food additive status or prior sanction status pursuant to this review shall be handled pursuant to §§ 170.35, 170.38, and 180.1 of this chapter. Affirmation of GRAS status shall be announced in part 184 or part 186 of this chapter.

* * * * *

(l) * * * Any change to the GRAS status of a food ingredient in parts 182, 184, or 186 of this chapter shall be accomplished pursuant to § 170.38.

■ 9. In § 170.35, revise paragraphs (a), (b)(1), (3), and (4), and remove paragraph (c) to read as follows:

§ 170.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, on his own initiative, may affirm that a substance that directly or indirectly becomes a component of food is GRAS under the conditions of its intended use.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS under the conditions of its intended use, he will place all of the data and information on which he relies on public file in the office of the Division of Dockets Management and will publish in the **Federal Register** a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

* * * * *

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS under the conditions of its intended use as described in § 170.30, he will publish a notice in the **Federal Register** listing the GRAS conditions of use of the substance in part 184 or part 186 of this chapter, as appropriate.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that a substance is GRAS under the conditions of its intended use and that it should be considered a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act, he shall publish a notice thereof in the **Federal Register** in accordance with § 170.38.

■ 10. In § 170.38, revise paragraph (a) to read as follows:

§ 170.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 170.35(b)(4), publish a notice in the **Federal Register** determining that a substance is not GRAS under the conditions of its intended use and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 11. Add subpart E, consisting of §§ 170.203 through 170.285, to read as follows:

Subpart E—Generally Recognized as Safe (GRAS) Notice

Sec.

170.203 Definitions.
170.205 Opportunity to submit a GRAS notice.
170.210 How to send your GRAS notice to FDA.
170.215 Incorporation into a GRAS notice.
170.220 General requirements applicable to a GRAS notice.
170.225 Part 1 of a GRAS notice: Signed statements and certification.
170.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.
170.235 Part 3 of a GRAS notice: Dietary exposure.
170.240 Part 4 of a GRAS notice: Self-limiting levels of use.
170.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.
170.250 Part 6 of a GRAS notice: Narrative.
170.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.
170.260 Steps you may take before FDA responds to your GRAS notice.
170.265 What FDA will do with a GRAS notice.
170.270 Procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture.
170.275 Public disclosure of a GRAS notice.
170.280 Submission of a supplement.
170.285 Disposition of pending GRAS affirmation petitions.

Subpart E—Generally Recognized as Safe (GRAS) Notice

§ 170.203 Definitions.

The definitions and interpretations of terms in § 170.3 apply to such terms when used in this subpart. The following definitions also apply:

Amendment means any data and information that you submit regarding a filed GRAS notice before we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

GRAS means generally recognized as safe.

GRAS notice means a submission that informs us of your view that a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is GRAS under the conditions of its intended use in accordance with § 170.30.

Notified substance means the substance that is the subject of your GRAS notice.

Notifier means the person (*e.g.,* an individual, partnership, corporation, association, or other legal entity) who is responsible for the GRAS notice, even if another person (such as an attorney, agent, or qualified expert) prepares or submits the notice or provides an opinion about the basis for a conclusion of GRAS status.

Qualified expert means an individual who is qualified by scientific training and experience to evaluate the safety of substances under the conditions of their intended use in food.

Supplement means any data and information that you submit regarding a filed GRAS notice after we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

We, our, and *us* refer to the United States Food and Drug Administration (FDA).

You and *your* refer to a notifier.

§ 170.205 Opportunity to submit a GRAS notice.

Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use.

§ 170.210 How to send your GRAS notice to FDA.

(a) Send your GRAS notice to the Office of Food Additive Safety (HFS–200), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Drive, College Park, MD 20740.

(b) When you submit your GRAS notice, you may do so either in an electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.

§ 170.215 Incorporation into a GRAS notice.

You may incorporate into your GRAS notice either specifically identified data and information that you previously submitted to the Center for Food Safety and Applied Nutrition (CFSAN), or specifically identified publicly available data and information submitted by another party, when such data and information remain in CFSAN's records, such as data and information contained in a previous GRAS notice or a food additive petition.

§ 170.220 General requirements applicable to a GRAS notice.

(a) A GRAS notice has seven parts as required by §§ 170.225 through 170.255. You must submit the data and information specified in each of these parts on separate pages or sets of pages.

(b) You must include each of the seven parts in your GRAS notice. If you do not include a part, you must include with your GRAS notice an explanation of why that part does not apply to your GRAS notice.

§ 170.225 Part 1 of a GRAS notice: Signed statements and certification.

(a) Part 1 of your GRAS notice must be dated and signed by a responsible official of your organization, or by your attorney or agent.

(b) Except as required by paragraph (c)(8) of this section, you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice.

(c) In Part 1 of your GRAS notice, you must:

(1) Inform us that you are submitting a GRAS notice in accordance with this subpart;

(2) Provide the name and address of your organization;

(3) Provide the name of the notified substance, using an appropriately descriptive term;

(4) Describe the intended conditions of use of the notified substance, including the foods in which the substance will be used, the levels of use in such foods, and the purposes for which the substance will be used, including, when appropriate, a description of a subpopulation expected to consume the notified substance;

(5) Inform us of the statutory basis for your conclusion of GRAS status (*i.e.,* through scientific procedures in accordance with § 170.30(a) and (b) or through experience based on common use in food in accordance with § 170.30(a) and (c));

(6) State your view that the notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the notified substance is GRAS under the conditions of its intended use;

(7) State that, if we ask to see the data and information that are the basis for your conclusion of GRAS status, either during or after our evaluation of your notice, you will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon our request, you will allow us to review and copy the data and information during customary business hours at the address you specify for where these data and information will be available to us; and

(B) Upon our request, you will provide us with a complete copy of the data and information either in an electronic format that is accessible for our evaluation or on paper;

(8) State your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the Freedom of Information Act, 5 U.S.C. 552 (*e.g.,* as trade secret or as commercial or financial information that is privileged or confidential).

(9) Certify that, to the best of your knowledge, your GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance;

(10) State both the name and position or title of the person who signs the GRAS notice; and

(11) When applicable, state as required by § 170.270 whether you:

(i) Authorize us to send any trade secrets to the Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture; or

(ii) Ask us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS.

§ 170.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.

In Part 2 of your GRAS notice, you must include:

(a) Scientific data and information that identifies the notified substance.

(1) Examples of appropriate data and information include the chemical name, applicable registry numbers (such as a Chemical Abstracts Service (CAS) registry number or an Enzyme Commission (EC) number), empirical formula, structural formula, quantitative composition, and characteristic properties.

(2) When the source of a notified substance is a biological material, you must include data and information sufficient to identify:

(i) The taxonomic source (*e.g.,* genus, species) including, as applicable, data and information at the sub-species level (*e.g.,* variety, strain);

(ii) The part of any plant or animal used as the source; and

(iii) Any known toxicants that could be in the source;

(b) A description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured;

(c) Specifications for food-grade material; and

(d) When necessary to demonstrate safety, relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.

§ 170.235 Part 3 of a GRAS notice: Dietary exposure.

In part 3 of your GRAS notice, you must provide data and information about dietary exposure (*i.e.,* the amount of relevant substances that consumers are likely to eat or drink as part of a total diet), regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food, as follows:

(a) You must provide an estimate of dietary exposure to the notified substance that includes exposure from its intended use and all sources in the diet; and

(b) When applicable, you must provide an estimate of dietary exposure to any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.,* hydrolytic products or reaction products);

(c) When applicable, you must provide an estimate of dietary exposure to any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.,* contaminants or by-products);

(d) You must describe the source of any food consumption data that you use to estimate dietary exposure in accordance with paragraphs (a) through (c) of this section; and

(e) You must explain any assumptions you made to estimate dietary exposure in accordance with paragraphs (a) through (c) of this section.

§ 170.240 Part 4 of a GRAS notice: Self-limiting levels of use.

In circumstances where the amount of the notified substance that can be added to food is limited because food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical, in Part 4 of your GRAS notice you must include data and information on such self-limiting levels of use.

§ 170.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.

If the statutory basis for your conclusion of GRAS status is through experience based on common use in food, in Part 5 of your GRAS notice you must include evidence of a substantial history of consumption of the notified substance for food use by a significant number of consumers prior to January 1, 1958.

§ 170.250 Part 6 of a GRAS notice: Narrative.

In Part 6 of your GRAS notice, you must include a narrative that provides the basis for your conclusion of GRAS status, in which:

(a)(1) You must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use. In your explanation, you must address the safety of the notified substance, considering all dietary sources and taking into account any chemically or pharmacologically related substances in such diet;

(2) In your explanation, you must identify what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are generally available, and what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are not generally available, by providing citations to the list of data and information that you include in Part 7 of your GRAS notice in accordance with § 170.255;

(b) You must explain how the generally available data and information that you rely on to establish safety in accordance with paragraph (a) of this section provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use;

(c) You must either:

(1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available; or

(2) State that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status;

(d) If you view any of the data and information in your notice as exempt from disclosure under the Freedom of Information Act, you must identify the specific data and information; and

(e) For non-public, safety-related data and information considered in reaching a conclusion of GRAS status, you must explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to such data and information.

§ 170.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.

(a) In part 7 of your GRAS notice, you must include a list of all of the data and information that you discuss in Part 6 of your GRAS notice to provide a basis for your view that the notified substance is safe under the conditions of its intended use as described in accordance with § 170.250(a)(1).

(b) You must specify which data and information that you list in accordance with paragraph (a) of this section are generally available, and which data and information are not generally available.

§ 170.260 Steps you may take before FDA responds to your GRAS notice.

(a) You may submit a timely amendment to your filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

(b) At any time before we respond to your GRAS notice in accordance with § 170.265(b)(1), you may request in writing that we cease to evaluate your GRAS notice. Your request does not preclude you from submitting a future GRAS notice in accordance with this subpart with respect to the notified substance.

§ 170.265 What FDA will do with a GRAS notice.

(a)(1) We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use.

(2) If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing.

(3) If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provides our reasons for not filing the submission as a GRAS notice.

(4) We will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter in accordance with paragraph (b)(1) of this section, if we deem that doing so is feasible within the timeframes established in paragraph (b) of this section. If we deem that considering your amendment is not feasible within the timeframes established in paragraph (b) of this section or if we have granted your request to cease to evaluate your notice, we will inform you that we are not considering your amendment.

(b)(1) Within 180 days of filing, we will respond to you by letter based on our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis.

(2) If we extend the timeframe, we will inform you in writing of the extension as soon as practicable but no later than within 180 days of filing.

(3) If you ask us to cease to evaluate your GRAS notice in accordance with § 170.260(b), we will send you a letter informing you of our decision regarding your request.

(c) If circumstances warrant, we will send you a subsequent letter about the notice.

§ 170.270 Procedures that apply when the intended conditions of use of a notified substance include use in a product or products subject to regulation by the Food Safety and Inspection Service (FSIS) of the United States Department of Agriculture.

If the intended conditions of use of the notified substance include use in a product or products subject to regulation by FSIS under statutes that it administers:

(a) When applicable, you must include in your GRAS notice a statement as to whether you:

(1) Authorize us to send any trade secrets to FSIS; or

(2) Ask us to exclude any trade secrets from the copy of the GRAS notice that we will send to FSIS.

(b)(1) We will forward a copy of a GRAS notice or relevant portions thereof to FSIS;

(2) We will exclude any trade secrets unless you have authorized us to do so in accordance with paragraph (a)(1) of this section; and

(c) We will ask FSIS to advise whether the intended conditions of use comply with applicable statutes and regulations, or, if not, whether the use of the substance would be permitted in products under FSIS' jurisdiction under specified conditions or restrictions.

(d) As appropriate, we will inform you of the advice we receive from FSIS in the letter we send you in accordance with § 170.265(b)(1).

§ 170.275 Public disclosure of a GRAS notice.

(a) The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice or incorporated into your GRAS notice) are:

(1) Considered a mandatory, rather than voluntary, submission for purposes of their status under the Freedom of Information Act and our public information requirements in part 20 of this chapter; and

(2) Available for public disclosure in accordance with part 20 of this chapter as of the date that we receive your GRAS notice.

(b) We will make the following readily accessible to the public:

(1) A list of filed GRAS notices, including the information described in § 170.225(c)(2) through (c)(5);

(2) The text of any letter that we issue under § 170.265(b)(1) or (c); and

(3) The text of any letter that we issue under § 170.265(b)(3) if we grant your request that we cease to evaluate your notice.

(c) We will disclose all remaining data and information that are not exempt from public disclosure in accordance with part 20 of this chapter.

§ 170.280 Submission of a supplement.

If circumstances warrant, you may submit a supplement to a filed GRAS notice after we respond to your notice by letter in accordance with § 170.265(b)(1) or cease to evaluate your notice in accordance with § 170.265(b)(3).

§ 170.285 Disposition of pending GRAS affirmation petitions.

Because the procedure to submit a GRAS notice is replacing the former process to submit a GRAS affirmation petition, the following will happen to a filed GRAS affirmation petition that is pending on October 17, 2016.

(a) On October 17, 2016, we will close the docket for any GRAS affirmation petition that is still pending as of October 17, 2016.

(b) Any person who submitted a GRAS affirmation petition described in this section may submit a GRAS notice as described in this subpart and request that we incorporate the GRAS affirmation petition as described in § 170.215.

PART 184—DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 12. The authority citation for part 184 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 13. In § 184.1, revise the first sentence of paragraph (a), and revise the fifth sentence and remove the last sentence of paragraph (b)(1) to read as follows.

§ 184.1 Substances added directly to human food affirmed as generally recognized as safe (GRAS).

(a) The direct human food ingredients listed in this part have been reviewed by the Food and Drug Administration and affirmed to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed. * * *

(b) * * *

(1) * * * In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall have a basis to conclude that that use is GRAS or shall use the ingredient in accordance with a food additive regulation. * * *

* * * * *

PART 186—INDIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

■ 14. The authority citation for part 186 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 371.

■ 15. In § 186.1, revise the first sentence of paragraph (a), and revise the fifth sentence and remove the last sentence of paragraph (b)(1) to read as follows.

§ 186.1 Substances added indirectly to human food affirmed as generally recognized as safe (GRAS).

(a) The indirect human food ingredients listed in this part have been reviewed by the Food and Drug Administration and affirmed to be generally recognized as safe (GRAS) for the purposes and under the conditions prescribed, providing they comply with the purity specifications listed in this part or, in the absence of purity specifications, are of a purity suitable for their intended use in accordance with § 170.30(h)(1) of this chapter. * * *

(b) * * *

(1) * * * In such a case, a manufacturer may not rely on the regulation as authorizing that use but shall have a basis to conclude that the use is GRAS or shall use the ingredient in accordance with a food additive regulation. * * *

* * * * *

PART 570—FOOD ADDITIVES

■ 16. The authority citation for part 570 continues to read as follows:

Authority: 21 U.S.C. 321, 341, 342, 346a, 348, 371.

■ 17. In § 570.3, revise paragraphs (f), (h), the first sentence of (i), and (k), and add paragraph (n) to read as follows:

§ 570.3 Definitions.

* * * * *

(f) *Common use in food* means a substantial history of consumption of a substance by a significant number of animals of the species to which the substance is intended to be fed (and, for food-producing animals fed with such substance, also means a substantial history of consumption by humans consuming human foods derived from those food-producing animals), prior to January 1, 1958.

* * * * *

(h) *Scientific procedures* include the application of scientific data (including, as appropriate, data from human, animal, analytical, or other scientific studies), information, and methods, whether published or unpublished, as well as the application of scientific principles, appropriate to establish the safety of a substance under the conditions of its intended use.

(i) *Safe* or *safety* means that there is a reasonable certainty in the minds of competent scientists that the substance is not harmful under the conditions of its intended use. * * *

* * * * *

(k) *General recognition of safety* shall be in accordance with § 570.30.

* * * * *

(n) *Food-producing animal* means an animal used to produce human food.

■ 18. In § 570.30, revise the last sentence of paragraph; (a); revise paragraphs (b) through (d); and revise the last sentence in paragraph (i) to read as follows:

§ 570.30 Eligibility for classification as generally recognized as safe (GRAS).

(a) * * * General recognition of safety requires common knowledge throughout the scientific community knowledgeable about the safety of substances directly or indirectly added to food that there is reasonable certainty that the substance is not harmful to either the target animal or to humans consuming human food derived from food-producing animals under the conditions of its intended use (see § 570.3(i)).

(b) General recognition of safety based upon scientific procedures shall require the same quantity and quality of scientific evidence as is required to obtain approval of a food additive. General recognition of safety through scientific procedures shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and shall be based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods.

(c)(1) General recognition of safety through experience based on common use in food prior to January 1, 1958, shall address safety for both the target animal and for humans consuming human food derived from food-producing animals and may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance in the same animal species prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.

(2) A substance used in food prior to January 1, 1958, may be generally recognized as safe through experience based on its common use in food when that use occurred exclusively or primarily outside of the United States if the information about the experience establishes that the substance is safe under the conditions of its intended use within the meaning of section 201(u) of the Federal Food, Drug, and Cosmetic Act (see also § 570.3(i)) for both the target animal and for humans consuming human food derived from food-producing animals. Common use in food prior to January 1, 1958, that occurred outside of the United States shall be documented by published or other information and shall be corroborated by information from a second, independent source that confirms the history and circumstances of use of the substance. The information used to document and to corroborate the history and circumstances of use of the substance must be generally available; that is, it must be widely available in the country in which the history of use has occurred and readily available to interested qualified experts in the United States. A person who concludes that a use of a substance is GRAS through experience based on its common use in food outside of the United States should notify FDA of that view in accordance with subpart E of this part.

(d) The food ingredients listed as GRAS in part 582 of this chapter or affirmed as GRAS in part 584 of this chapter do not include all substances that are generally recognized as safe for their intended use in food. Because of the large number of substances the intended use of which results or may reasonably be expected to result, directly or indirectly, in their becoming a component or otherwise affecting the characteristics of food, it is impracticable to list all such substances that are GRAS. A food ingredient of natural biological origin that has been widely consumed for its nutrient properties in the United States prior to January 1, 1958, without known detrimental effects, which is subject only to conventional processing as practiced prior to January 1, 1958, and for which no known safety hazard exists, will ordinarily be regarded as GRAS without specific inclusion in part 582 or part 584 of this chapter.

* * * * *

(i) * * * Any use of such an ingredient not in full compliance with each such established limitation shall require a food additive regulation.

* * * * *

■ 19. In § 570.35, revise paragraphs (a), (b)(1), (3), and (4), and remove paragraph (c) to read as follows:

§ 570.35 Affirmation of generally recognized as safe (GRAS) status.

(a) The Commissioner, on his own initiative, may affirm that a substance that directly or indirectly becomes a component of food is GRAS under the conditions of its intended use.

(b)(1) If the Commissioner proposes on his own initiative that a substance is entitled to affirmation as GRAS under the conditions of its intended use, he will place all of the data and information on which he relies on public file in the office of the Division of Dockets Management and will publish in the **Federal Register** a notice giving the name of the substance, its proposed uses, and any limitations proposed for purposes other than safety.

* * * * *

(3) The Commissioner will evaluate all comments received. If he concludes that there is convincing evidence that the substance is GRAS under the conditions of its intended use as described in § 570.30, he will publish a notice in the **Federal Register** listing the GRAS conditions of use in this subchapter E.

(4) If, after evaluation of the comments, the Commissioner concludes that there is a lack of convincing evidence that the substance is GRAS under the conditions of its intended use and that it should be considered a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act, he shall publish a notice thereof in the **Federal Register** in accordance with § 570.38.

■ 20. In § 570.38, revise paragraph (a) to read as follows:

§ 570.38 Determination of food additive status.

(a) The Commissioner may, in accordance with § 570.35(b)(4), publish a notice in the **Federal Register** determining that a substance is not GRAS under the conditions of its intended use and is a food additive subject to section 409 of the Federal Food, Drug, and Cosmetic Act.

* * * * *

■ 21. Add and reserve subparts C and D.

■ 22. Add subpart E, consisting of §§ 570.203 through 570.280, to read as follows:

Subpart E—Generally Recognized as Safe (GRAS) Notice

Sec.
570.203 Definitions.
570.205 Opportunity to submit a GRAS notice.

570.210 How to send your GRAS notice to FDA.
570.215 Incorporation into a GRAS notice.
570.220 General requirements applicable to a GRAS notice.
570.225 Part 1 of a GRAS notice: Signed statements and certification.
570.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.
570.235 Part 3 of a GRAS notice: Target animal and human exposures.
570.240 Part 4 of a GRAS notice: Self-limiting levels of use.
570.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.
570.250 Part 6 of a GRAS notice: Narrative.
570.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.
570.260 Steps you may take before FDA responds to your GRAS notice.
570.265 What FDA will do with a GRAS notice.
570.275 Public disclosure of a GRAS notice.
570.280 Submission of a supplement.

Subpart E—Generally Recognized as Safe (GRAS) Notice

§ 570.203 Definitions.

The definitions and interpretations of terms in § 570.3 apply to such terms when used in this subpart. The following definitions also apply:

Amendment means any data and information that you submit regarding a filed GRAS notice before we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

GRAS means generally recognized as safe.

GRAS notice means a submission that informs us of your view that a substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the substance is GRAS under the conditions of its intended use in accordance with § 570.30.

Notified substance means the substance that is the subject of your GRAS notice.

Notifier means the person (*e.g.,* an individual, partnership, corporation, association, or other legal entity) who is responsible for the GRAS notice, even if another person (such as an attorney, agent, or qualified expert) prepares or submits the notice or provides an opinion about the basis for a conclusion of GRAS status.

Qualified expert means an individual who is qualified by scientific training and experience to evaluate the safety of substances under the conditions of their intended use in animal food.

Supplement means any data and information that you submit regarding a filed GRAS notice after we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

We, our, and *us* refer to the United States Food and Drug Administration (FDA).

You and *your* refer to a notifier.

§ 570.205 Opportunity to submit a GRAS notice.

Any person may notify FDA of a view that a substance is not subject to the premarket approval requirements of section 409 of the Federal Food, Drug, and Cosmetic Act based on that person's conclusion that the substance is GRAS under the conditions of its intended use.

§ 570.210 How to send your GRAS notice to FDA.

(a) Send your GRAS notice to the Division of Animal Feeds (HFV–220), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855.

(b) When you submit your GRAS notice, you may do so either in an electronic format that is accessible for our evaluation or on paper. If you send your GRAS notice on paper, a single paper copy is sufficient.

§ 570.215 Incorporation into a GRAS notice.

You may incorporate into your GRAS notice either specifically identified data and information that you previously submitted to the Center for Veterinary Medicine (CVM), or specifically identified publicly available data and information submitted by another party, when such data and information remain in CVM's records, such as data and information contained in a previous GRAS notice or a food additive petition.

§ 570.220 General requirements applicable to a GRAS notice.

(a) A GRAS notice has seven parts as required by §§ 570.225 through 570.255. You must submit the data and information specified in each of these parts on separate pages or sets of pages.

(b) You must include each of the seven parts in your GRAS notice. If you do not include a part, you must include with your GRAS notice an explanation of why that part does not apply to your GRAS notice.

§ 570.225 Part 1 of a GRAS notice: Signed statements and certification.

(a) Part 1 of your GRAS notice must be dated and signed by a responsible official of your organization, or by your attorney or agent.

(b) Except as required by paragraph (c)(8) of this section, you must not include any information that is trade secret or confidential commercial information in Part 1 of your GRAS notice.

(c) In Part 1 of your GRAS notice, you must:

(1) Inform us that you are submitting a GRAS notice in accordance with this subpart;

(2) Provide the name and address of your organization;

(3) Provide the name of the notified substance, using an appropriately descriptive term;

(4) Describe the intended conditions of use of the notified substance, including stating whether the substance will be added to food (including drinking water) for animals in which the substance will be used; identifying the foods to which it will be added, the levels of use in such foods, and the animal species for which these foods are intended (including, when appropriate, a description of a subpopulation expected to consume the notified substance); and the purposes for which the substance will be used;

(5) Inform us of the statutory basis for your conclusion of GRAS status (*i.e.,* through scientific procedures in accordance with § 570.30(a) and (b) or through experience based on common use in animal food in accordance with § 570.30(a) and (c));

(6) State your view that the notified substance is not subject to the premarket approval requirements of the Federal Food, Drug, and Cosmetic Act based on your conclusion that the notified substance is GRAS under the conditions of its intended use;

(7) State that, if we ask to see the data and information that are the basis for your conclusion of GRAS status, either during or after our evaluation of your notice, you will:

(i) Agree to make the data and information available to us; and

(ii) Agree to both of the following procedures for making the data and information available to us:

(A) Upon our request, you will allow us to review and copy the data and information during customary business hours at the address you specify for where these data and information will be available to us; and

(B) Upon our request, you will provide us with a complete copy of the data and information either in an electronic format that is accessible for our evaluation or on paper;

(8) State your view as to whether any of the data and information in Parts 2 through 7 of your GRAS notice are exempt from disclosure under the

Freedom of Information Act, 5 U.S.C. 552 (*e.g.,* as trade secret or as commercial or financial information that is privileged or confidential);

(9) Certify that, to the best of your knowledge, the GRAS notice is a complete, representative, and balanced submission that includes unfavorable information, as well as favorable information, known to you and pertinent to the evaluation of the safety and GRAS status of the use of the substance; and

(10) State both the name and the position or title of the person who signs the GRAS notice.

§ 570.230 Part 2 of a GRAS notice: Identity, method of manufacture, specifications, and physical or technical effect.

In Part 2 of your GRAS notice, you must include:

(a) Scientific data and information that identifies the notified substance.

(1) Examples of appropriate data and information include the chemical name, applicable registry numbers (such as a Chemical Abstracts Service (CAS) registry number or an Enzyme Commission (EC) number), empirical formula, structural formula, quantitative composition, and characteristic properties.

(2) When the source of a notified substance is a biological material, you must include data and information sufficient to identify:

(i) The taxonomic source (*e.g.,* genus, species), including as applicable data and information at the sub-species level (*e.g.,* variety, strain);

(ii) The part of any plant or animal used as the source; and

(iii) Any known toxicants that could be in the source;

(b) A description of the method of manufacture of the notified substance in sufficient detail to evaluate the safety of the notified substance as manufactured;

(c) Specifications for material that is of appropriate grade for use in animal food; and

(d) When necessary to demonstrate safety, relevant data and information bearing on the physical or other technical effect the notified substance is intended to produce, including the quantity of the notified substance required to produce such effect.

§ 570.235 Part 3 of a GRAS notice: Target animal and human exposures.

In part 3 of your GRAS notice, you must provide data and information about exposure to the target animal and to humans consuming human food derived from food-producing animals, regardless of whether your conclusion of GRAS status is through scientific procedures or through experience based on common use in food, as follows:

(a) For exposure to the target animal, you must provide:

(1) The amount of the notified substance that different target animal species are likely to consume in the animal food (including drinking water) as part of the animal's total diet, including the intended use and all other sources in the total diet; and

(2) When applicable, the amount of any other substance that is expected to be formed in or on food because of the use of the notified substance (*e.g.,* hydrolytic products or reaction products);

(3) When applicable, the amount of any other substance that is present with the notified substance either naturally or due to its manufacture (*e.g.,* contaminants or by-products);

(4) The data and information you rely on to establish the amount of the notified substance and the amounts of any other substance in accordance with paragraphs (a)(1) through (a)(3) of this section that different target animal species are likely to consume in the animal food (including drinking water) as part of the animal's total diet; and

(b) When the intended use is in food for food-producing animals, you must provide:

(1) The potential quantities of any residues that humans may be exposed to in edible animal tissues, including:

(i) Residues of the notified substance;

(ii) Residues of any other substance that is expected to be formed in or on the animal food because of the use of the notified substance; and

(iii) Residues from any other substance that is present with the notified substance whether naturally, due to its manufacture (*e.g.,* contaminants or by-products), or produced as a metabolite in edible animal tissues when the notified substance is consumed by a food-producing animal; and

(2) The data and information you rely on to establish, in accordance with paragraph (b)(1) of this section, the potential quantities of any residues that humans may be exposed to in edible animal tissues.

§ 570.240 Part 4 of a GRAS notice: Self-limiting levels of use.

In circumstances where the amount of the notified substance that can be added to animal food is limited because animal food containing levels of the notified substance above a particular level would become unpalatable or technologically impractical, in Part 4 of your GRAS notice you must include data and information on such self-limiting levels of use.

§ 570.245 Part 5 of a GRAS notice: Experience based on common use in food before 1958.

If the statutory basis for your conclusion of GRAS status is through experience based on common use in animal food, in Part 5 of your GRAS notice you must include evidence of a substantial history of consumption of the notified substance for food use by a significant number of animals of the species to which the substance is intended to be fed prior to January 1, 1958, and evidence of a substantial history of consumption by humans consuming human foods derived from food-producing animals prior to January 1, 1958.

§ 570.250 Part 6 of a GRAS notice: Narrative.

In Part 6 of your GRAS notice, you must include a narrative that provides the basis for your conclusion of GRAS status, in which:

(a)(1) You must explain why the data and information in your notice provide a basis for your view that the notified substance is safe under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals. In your explanation, you must address the safety of the notified substance, considering all animal food (including drinking water) as part of the animal's total diet, taking into account any chemically or pharmacologically related substances in such diet. In your explanation, you must also address the safety of the notified substance in regard to human exposure, considering all dietary sources and taking into account any chemically or pharmacologically related substances;

(2) In your explanation, you must identify what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are generally available, and what specific data and information that you discuss in accordance with paragraph (a)(1) of this section are not generally available, by providing citations to the list of data and information that you include in Part 7 of your GRAS notice in accordance with § 570.255;

(b) You must explain how the generally available data and information that you rely on to establish safety in accordance with paragraph (a) of this section provide a basis for your conclusion that the notified substance is generally recognized, among qualified experts, to be safe under the conditions of its intended use for both the target animal and for humans consuming human food derived from food-producing animals;

(c) You must either:

(1) Identify, discuss, and place in context, data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status, regardless of whether those data and information are generally available; or

(2) State that you have reviewed the available data and information and are not aware of any data and information that are, or may appear to be, inconsistent with your conclusion of GRAS status;

(d) If you view any of the data and information in your notice as exempt from disclosure under the Freedom of Information Act, you must identify the specific data and information; and

(e) For non-public, safety-related data and information considered in reaching a conclusion of GRAS status, you must explain how there could be a basis for a conclusion of GRAS status if qualified experts do not have access to such data and information.

§ 570.255 Part 7 of a GRAS notice: List of supporting data and information in your GRAS notice.

(a) In part 7 of your GRAS notice, you must include a list of all of the data and information that you discuss in Part 6 of your GRAS notice to provide a basis for your view that the notified substance is safe under the conditions of its intended use as described in accordance with § 570.250(a)(1).

(b) You must specify which data and information that you list in accordance with paragraph (a) of this section are generally available, and which data and information are not generally available.

§ 570.260 Steps you may take before FDA responds to your GRAS notice.

(a) You may submit a timely amendment to your filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

(b) At any time before we respond to your notice by letter in accordance with § 570.265(b)(1), you may request in writing that we cease to evaluate your GRAS notice. Your request does not preclude you from submitting a future GRAS notice in accordance with this subpart with respect to the notified substance.

§ 570.265 What FDA will do with a GRAS notice.

(a)(1) We will conduct an initial evaluation of your submission to determine whether to file it as a GRAS notice for evaluation of your view that the notified substance is GRAS under the conditions of its intended use.

(2) If we file your submission as a GRAS notice, we will send you a letter that informs you of the date of filing.

(3) If we do not file your submission as a GRAS notice, we will send you a letter that informs you of that fact and provide our reasons for not filing the submission as a GRAS notice.

(4) We will consider any timely amendment that you submit to a filed GRAS notice, to update your GRAS notice or in response to a question from us, before we respond to you by letter in accordance with paragraph (b)(1) of this section, if we deem that doing so is feasible within the timeframes established in paragraph (b) of this section. If we deem that considering your amendment is not feasible within the timeframes established in paragraph (b) of this section or if we have granted your request to cease to evaluate your notice, we will inform you that we are not considering your amendment.

(b)(1) Within 180 days of filing, we will respond to you by letter based on our evaluation of your notice. We may extend the 180 day timeframe by 90 days on an as needed basis.

(2) If we extend the timeframe, we will inform you in writing of the extension as soon as practicable but no later than within 180 days of filing.

(3) If you ask us to cease to evaluate your GRAS notice in accordance with § 570.260(b), we will send you a letter informing you of our decision regarding your request.

(c) If circumstances warrant, we will send you a subsequent letter about the notice.

§ 570.275 Public disclosure of a GRAS notice.

(a) The data and information in a GRAS notice (including data and information submitted in any amendment or supplement to your GRAS notice, or incorporated into your GRAS notice) are:

(1) Considered a mandatory, rather than voluntary, submission for purposes of their status under the Freedom of Information Act and our public information requirements in part 20 of this chapter; and

(2) Available for public disclosure in accordance with part 20 of this chapter as of the date that we receive your GRAS notice.

(b) We will make the following readily accessible to the public:

(1) A list of filed GRAS notices, including the information described in § 570.225(c)(2) through (c)(5);

(2) The text of any letter that we issue under § 570.265(b)(1) or (c); and

(3) The text of any letter that we issue under § 570.265(b)(3) if we grant your request that we cease to evaluate your notice.

(c) We will disclose all remaining data and information that are not exempt from public disclosure in accordance with part 20 of this chapter.

§ 570.280 Submission of a supplement.

If circumstances warrant, you may submit a supplement to a filed GRAS notice after we respond to your notice by letter in accordance with § 570.265(b)(1) or cease to evaluate your notice in accordance with § 570.265(b)(3).

Dated: August 8, 2016.

Jeremy Sharp,

Deputy Commissioner for Policy, Planning, Legislation and Analysis.

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Part IV

Department of the Interior

Fish and Wildlife Service

50 CFR Part 17
Endangered and Threatened Wildlife and Plants; Threatened Status for *Lepidium papilliferum* (Slickspot Peppergrass) Throughout Its Range; Final Rule

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

[Docket No. FWS–R1–ES–2013–0117; MO 92210–0–0008 B2]

RIN 1018–BA27

Endangered and Threatened Wildlife and Plants; Threatened Status for *Lepidium papilliferum* (Slickspot Peppergrass) Throughout Its Range

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Final rule.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), determine threatened status under the Endangered Species Act of 1973, as amended, for *Lepidium papilliferum* (slickspot peppergrass), a plant species from the State of Idaho. *Lepidium papilliferum* was added to the List of Endangered and Threatened Plants as a threatened species through the publication of a final rule on October 8, 2009. The Idaho District Court subsequently vacated the listing of *L. papilliferum* and remanded the final rule to the Service for the purpose of reconsidering the definition of the "foreseeable future" in regard to this particular species. The Court did not question the science underlying the Service's determination of threatened status for the species. We have reconsidered the definition of "foreseeable future" for *L. papilliferum* in this final rule; therefore, it addresses the Court's remand. The effect of this regulation is to reinstate threatened species status of *L. papilliferum* on the List of Endangered and Threatened Plants.

DATES: This rule becomes effective September 16, 2016.

ADDRESSES: This final rule is available on the Internet *at http://www.regulations.gov* and *http://www.fws.gov/idaho.* Some of the comments and materials we received, as well as supporting documentation we used in preparing this rule, are available for public inspection at *http://www.regulations.gov,* under Docket Number FWS–R1–ES–2013–0117. All of the comments, materials, and documentation that we considered in this rulemaking are available by appointment, during normal business hours at: U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Room 368, Boise, ID 83709; telephone 208–378–5243; facsimile 208–378–5262.

FOR FURTHER INFORMATION CONTACT: Dennis Mackey, Acting State Supervisor, U.S. Fish and Wildlife Service, Idaho Fish and Wildlife Office, 1387 S. Vinnell Way, Room 368, Boise, ID 83709; telephone 208–378–5243; facsimile 208–378–5262. If you use a telecommunications device for the deaf (TDD), call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

SUPPLEMENTARY INFORMATION:

Executive Summary

Why we need to publish a rule. Under the Endangered Species Act of 1973, as amended (ESA or Act), a species may warrant protection through listing if it is endangered or threatened throughout all or a significant portion of its range. Listing a species as an endangered or threatened species can only be completed by issuing a rule.

This rule reaffirms the listing of *Lepidium papilliferum* (slickspot peppergrass) as a threatened species throughout its range, as initially published on October 8, 2009 (74 FR 52014).

Purpose of this document. We are responding to the U.S. District Court for the District of Idaho's August 8, 2012, Memorandum Decision and Order vacating our October 8, 2009, final rule listing *Lepidium papilliferum* (slickspot peppergrass) as a threatened species (74 FR 52014) (2009 final listing rule) and remanding the rule to the Service for further consideration consistent with the Court's decision. The Act defines an endangered species as any species that is "in danger of extinction throughout all or a significant portion of its range" and a threatened species as any species "that is likely to become endangered throughout all or a significant portion of its range within the foreseeable future." The Act does not define the term "foreseeable future." With respect to the Service's finding of threatened status for *L. papilliferum,* the Court was supportive, stating that ". . . the Service's finding underlying the above conclusion [that *L. papilliferum* is likely to become an endangered species within the foreseeable future] are (*sic*) supported by the administrative record and entitled to deference." *Otter* v. *Salazar,* Case No. 1:11–cv–358–CWD, at 50 (D. Idaho, Aug. 8, 2012) *(Otter* v. *Salazar).* However, the Court took issue with the Service's application of the concept of the "foreseeable future" in the 2009 final listing rule (74 FR 52014, October 8, 2009). Although it found "no problem with the agency's science," the Court stated that "without a viable definition of foreseeable future, there can be no listing under the ESA." *Otter* v. *Salazar,* at 55. Based on this conclusion, the Court vacated the 2009 listing determination and remanded it to the Secretary for further consideration consistent with the Court's decision.

In order to ensure that our present determination remains based on the best scientific and commercial data available, we have evaluated any new scientific information that may have become available since our 2009 final listing rule (74 FR 52014, October 8, 2009), and re-evaluated the status of *Lepidium papilliferum* under the Act with an amended definition of the foreseeable future, consistent with the Court's opinion and as applied specifically to this species.

The basis for our action. Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered species or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination. We have determined that *Lepidium papilliferum* meets the definition of a threatened species under the Act, based on the present or threatened destruction, modification, or curtailment of its habitat and range due to the increased frequency and extent of wildfires under a wildfire regime modified and exacerbated by the spread of invasive nonnative plants, particularly nonnative annual grasses such as *Bromus tectorum* (cheatgrass). In addition, even under conservative projections of the consequences of future climate change, the threats posed by wildfire and the invasion of *B. tectorum* are expected to further increase into the future. Other threats to the species include competition and displacement by nonnative plant species, development, potential seed predation by harvester ants, and habitat fragmentation and isolation of small populations.

Public Comment. We sought comment on our interpretation of the foreseeable future as it applies specifically to *Lepidium papilliferum,* and solicited any new scientific and commercial data that may have become available since the publication of our October 8, 2009, final listing rule (74 FR 52014). The initial comment period on the reconsideration of final rule for *Lepidium papilliferum* was open for 30 days, from February 12, 2014, through March 14, 2014 (79 FR 8416, February 12, 2014). On April 21, 2014, we reopened the comment period for an additional 45 days, through June 5, 2014 (79 FR 22076). In developing this final rule, we considered all comments and information received during the comment periods.

Previous Federal Actions

On July 15, 2002, we proposed to list *Lepidium papilliferum* as an endangered species (67 FR 46441). On January 12, 2007, we published a document in the **Federal Register** withdrawing the proposed rule (72 FR 1622), based on a determination at that time that listing was not warranted (for a description of Federal actions concerning *L. papilliferum* between the 2002 proposal to list and the 2007 withdrawal, please refer to the 2007 withdrawal document). On April 6, 2007, Western Watersheds Project filed a lawsuit challenging our decision to withdraw the proposed rule to list *L. papilliferum.* On June 4, 2008, the U.S. District Court for the District of Idaho (Court) reversed the decision to withdraw the proposed rule, with directions that the case be remanded to the Service for further consideration consistent with the Court's opinion (*Western Watersheds Project* v. *Kempthorne,* Case No. CV 07–161–E–MHW (D. Idaho)).

After issuance of the Court's remand order, we published a public notification of the reinstatement of our July 15, 2002, proposed rule to list *Lepidium papilliferum* as an endangered species and announced the reopening of a public comment period on September 19, 2008 (73 FR 54345). To ensure that our review of the species' status was based on complete information, we announced another reopening of the comment period on March 17, 2009 (74 FR 11342). On October 8, 2009, we published a final rule (74 FR 52014) listing *L. papilliferum* as a threatened species throughout its range.

On November 16, 2009, Idaho Governor C. L. ''Butch'' Otter, the Idaho Office of Species Conservation, Theodore Hoffman, Scott Nicholson, and L.G. Davison & Sons, Inc., filed a complaint in the U.S. District Court for the District of Columbia challenging the 2009 final listing rule (74 FR 52014, October 8, 2009) under the Administrative Procedure Act and the Endangered Species Act. Subsequently, the issue was transferred to the U.S. District Court for the District Court of Idaho (Court), and the parties involved consented to proceed before a Magistrate Judge. On August 8, 2012, the Court vacated the final rule listing *Lepidium papilliferum* as a threatened species under the Act, with directions that the case be remanded to the Service for further consideration consistent with the Court's opinion. *Otter* v. *Salazar,* Case No. 1:11–cv–358–CWD (D. Idaho).

On February 12, 2014, we published in the **Federal Register** a proposed reconsideration of the final rule and request for comments (79 FR 8416). That document presented the Service's interpretation of the term ''foreseeable future'' as it applies specifically to *Lepidium papilliferum* and, based upon an evaluation of threats to the species under this timeframe, proposed to reinstate threatened status for the species. We sought public input on our definition of the foreseeable future for *L. papilliferum,* as well as on our proposed determination to reinstate threatened status for the species, during two public comment periods. The first comment period opened with publication of the reconsideration of final rule on February 12, 2014 (79 FR 8416), and closed on March 14, 2014. On April 21, 2014, in response to a request from the Idaho Governor's Office of Species Conservation, we reopened the comment period for an additional 45 days (79 FR 22076); that comment period closed on June 5, 2014.

Subsequent to the October 8, 2009, listing of *Lepidium papilliferum* as a threatened species (74 FR 52014), but prior to the August 8, 2012, Court vacatur of that final rule, we published a proposed rule to designate critical habitat for *L. papilliferum* (76 FR 27184, May 10, 2011). We suspended rulemaking on the proposed critical habitat following the Court's ruling vacating the listing. However, on February 12, 2014, concurrent with our publication of the proposed reconsideration of the listing, we published a revision of the proposed critical habitat for *L. papilliferum* (79 FR 8402; please see that document for a summary of all comment periods associated with the proposed critical habitat rule). We will finalize our critical habitat designation for *L. papilliferum* subsequent to this rulemaking.

In this final rule, after considering all comments and information received, we have concluded that threatened status should be reinstated for *Lepidium papilliferum,* and reinstate its listing as a threatened species on the Federal List of Endangered and Threatened Plants, as originally published on October 8, 2009 (74 FR 52014).

Background and New Information

A complete description of *Lepidium papilliferum,* including a discussion of its life history, ecology, habitat requirements, and monitoring of extant populations, can be found in the October 8, 2009, final listing rule (74 FR 52014). However, to ensure that we are considering the best scientific and commercial data available in our final decision, here we present new scientific information that has become available to us since our 2009 determination of threatened status, and evaluate that new information in light of our previous conclusions regarding the status of the species.

New Information Related to the Listing of Lepidium papilliferum

We have evaluated information presented in the 2009 final listing rule (74 FR 52014, October 8, 2009), as well as new information, regarding population status, trends, or threats, that has become available since 2009, including current element occurrence (EO) data provided to us by the Idaho Fish and Wildlife Information System (IFWIS) database (formerly the Idaho Natural Heritage Program database), updated fire-history data, the new rangewide Habitat Integrity and Population (HIP) monitoring data, information on current developments being proposed within the range of *Lepidium papilliferum,* and the most current data on seed predation by Owyhee harvester ants (*Pogonomyrmex salinus*), as described in the Factors Affecting the Species section, below.

Relatively limited new data regarding population abundance or trends have become available since our 2009 final listing rule (74 FR 52014, October 8, 2009). In 2011, 2012, and 2013 the total number of *Lepidium papilliferum* plants counted was the lowest since 2005, when complete counts for this species were initiated (16,462 plants in 2011; 9,245 plants in 2012; and 6,351 in 2013) (Kinter 2012, *in litt.;* Kinter 2015, *in litt.*). In 2014, however, 45,569 total plants were counted, which represented the third highest number of plants observed over the 10 years of HIP monitoring (Kinter 2015, *in litt.*). Previously, the lowest total number of plants counted occurred in 2006, with 17,543 plants, and the highest count was in 2010, with 58,921 plants (Idaho Department of Fish and Game (IDFG) 2012, p. 5). Meyer *et al.* (2005, p. 21) suggest that *L. papilliferum* relies on years with extremely favorable climatic elements to resupply the seed bank (*i.e.,* high bloom years with good weather), and during unfavorable years, it is dependent upon a persistent seed bank to maintain the population. The large differences in abundance seen over the past few years is thus not unexpected, and is consistent with our earlier observation that the extreme variability in annual counts poses a challenge in terms of assessing trend information (74 FR 52014, p. 52024; October 8, 2009).

In 2009, there were 80 extant *Lepidium papilliferum* EOs documented according to IFWIS data. Survey efforts over the past few years have located additional *L. papilliferum* occupied sites. According to IFWIS data, some existing EOs have been expanded (and in some cases merged with other EOs to meet the definition of an EO, by grouping occupied slickspots that occur within 1 kilometer (km) (0.6 miles (mi)) of each other), and 11 new EOs have been located. According to the most recent IFWIS data, there are now 91 extant *L. papilliferum* EOs. The discovery of some new occupied sites is not unexpected, given that not all potential *L. papilliferum* habitats in southwest Idaho have been surveyed. While the discovery of these new sites is encouraging, they are located near or in the vicinity of existing EOs, and, therefore, do not expand the known range of the species. Furthermore, they are all subject to the same threats affecting the species, and for the EOs that have been ranked, their associated ranks indicate they are not high-quality EOs. The existing EOs have not been re-ranked since 2005; however, the ranks given to the new EOs include one BC, one BD, three C, two CD, and one D. Three additional EOs are currently unranked (IFWIS data from January 2015). See the Monitoring of *Lepidium papilliferum* Populations section in the October 8, 2009, final listing rule (74 FR 52014) for a more detailed discussion of EOs and an explanation of the ranking system.

As discussed below in the section Factors Affecting the Species, the new information is consistent with our 2009 conclusions on the present distribution of *Lepidium papilliferum,* its status and population trends, and how the various threat factors are affecting the species.

Foreseeable Future

As indicated earlier, the Act defines a "threatened species" as any species (or subspecies or, for vertebrates, distinct population segments) that is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range. The Act does not define the term "foreseeable future." In a general sense, the foreseeable future is the period of time over which events can reasonably be anticipated; in the context of the definition of "threatened species," the Service interprets the foreseeable future as the extent of time over which the Secretary can reasonably rely on predictions about the future in making determinations about the future conservation status of the species. It is important to note that references to "reliable predictions" are not meant to refer to reliability in a statistical sense of confidence or significance; rather the words "rely" and "reliable" are intended to be used according to their common, non-technical meanings in ordinary usage. In other words, we consider a prediction to be reliable if it is reasonable to depend upon it in making decisions, and if that prediction does not extend past the support of scientific data or reason so as to venture into the realm of speculation.

In considering threats to the species and whether they rise to the level such that listing the species as a threatened species or endangered species is warranted, we assess factors such as the imminence of the threat (is it currently affecting the species or, if not, when do we expect the effect from the threat to commence, and whether it is reasonable to expect the threat to continue into the future), the scope or extent of the threat, the severity of the threat, and the synergistic effects of all threats combined. If we determine that the species is not currently in danger of extinction, then we must determine whether, based upon the nature of the threats, it is reasonable to anticipate that the species may become in danger of extinction within the foreseeable future. As noted in the 2009 Department of the Interior Solicitor's opinion on foreseeable future, "in some cases, quantifying the foreseeable future in terms of years may add rigor and transparency to the Secretary's analysis if such information is available. Such definitive quantification, however, is rarely possible and not required for a foreseeable future analysis" (M–37021, January 16, 2009; p. 9), available at *https://solicitor.doi.gov/opinions/M-37021.pdf.*

In some specific cases where extensive data were available to allow for the modeling of extinction probability over various time periods (*e.g.,* greater sage-grouse (75 FR 13910; March 23, 2010), the Service has provided quantitative estimates of what may be considered to constitute the foreseeable future. We do not have such data available for *Lepidium papilliferum.* Therefore, our analysis of the foreseeable future for the purposes of assessing the status of *L. papilliferum* must rely on the foreseeability of the relevant threats to the species over time, as described by the Solicitor's opinion (M–37021, January 16, 2009; p. 8). The foreseeable future extends only so far as the Secretary can explain reliance on the data to formulate a reliable prediction, based on the extent or nature of the data currently available, and to extrapolate any trend beyond that point would constitute speculation.

In earlier evaluations of the status of *Lepidium papilliferum,* the Service assembled panels of species and ecosystem experts to assist in our review through a structured decision-making process. As part of those evaluations, to help inform the decisions to be made by the Service managers, experts were asked to provide their best estimate of a timeframe for extinction of *L. papilliferum,* and were allowed to distribute points between various predetermined time categories, or to assign an extinction probability of low, medium, or high between time categories (*e.g.,* 1 to 20 years, 21 to 40 years, 41 to 60 years, 61 to 80 years, 81 to 100 years, 101 to 200 years, and 200 years and beyond). We note that this type of exercise was not intended to provide a precise quantitative estimate of the foreseeable future, nor was it meant to provide the definitive answer as to whether *L. papilliferum* is likely to become an endangered species within the foreseeable future. Rather, this type of exercise is used to help inform Service decision-makers, and ultimately the Secretary, as to whether there is broad agreement amongst the experts as to extinction probability within a certain timeframe.

In fact, the species experts expressed widely divergent opinions on extinction probabilities over various timeframes. As an example, in 2006, the estimated timeframes for extinction from seven different panel members fell into every time category presented ranging from 21 to 40 years up to 101 to 200 years. Because the species experts' divergent predictions were based on "reasonable, best educated guesses," we did not consider the range of timeframes to represent a prediction that can be reasonably relied upon to make a listing determination. As noted in the Solicitor's opinion, "the mere fact that someone has made a prediction concerning the future does not mean that the thing predicted is foreseeable for the purpose of making a listing determination under section 4 of the ESA" (M–37021, January 16, 2009; p. 10).

In our October 8, 2009, final listing rule (74 FR 52014), we did not present species experts with predetermined potential timeframes within which to estimate extinction probability for the species. Rather, we asked peer reviewers to provide us with their estimated projection of a time period for reliably predicting threat effects or extinction risk for the species. In response, most peer reviewers declined, stating that such future projections were likely speculative. One peer reviewer suggested that, given current trends in habitat loss and degradation, *L. papilliferum* "is likely at a tipping point in terms of its prospect for survival," and doubted that the species would persist in sustainable numbers beyond the next 50 to 75 years (74 FR 52055, October 8, 2009).

As suggested in the Solicitor's opinion, for the purposes of the present analysis, we are relying on an evaluation of the foreseeability of threats and the foreseeability of the effect of the threats on the species, extending this time period out only so far as we can rely on the data to formulate reliable predictions about the status of the species, and not extending so far as to venture into the realm of speculation. Therefore, in the case of *Lepidium papilliferum,* we conclude that the foreseeable future is that period of time within which we can reliably predict whether or not *L. papilliferum* is likely to become an endangered species as a result of the effects of wildfire, invasive nonnative plants, and other threats to the species. As explained below, with respect to the principal threat factors, the foreseeable future for *L. papilliferum* is at least 50 years.

Factors Affecting the Species

Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. The Service may determine a species is an endangered species or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

A detailed discussion and analysis of each of the threat factors for *Lepidium papilliferum* can be found in the 2009 final listing rule (74 FR 52014, October 8, 2009). For the purpose of this document, we are limiting our discussion of foreseeable future to the threats we consider significant in terms of contributing to the present or threatened destruction, modification, or curtailment of *L. papilliferum's* habitat or range, as identified in that final listing rule. These include the two primary threat factors: Altered wildfire regime (increasing frequency, size, and duration of wildfires), and invasive, nonnative plant species (*e.g., Bromus tectorum*), both of which are further exacerbated by climate change; as well as contributing threat factors of planned or proposed development, habitat fragmentation and isolation, and the emerging threat from seed predation by Owyhee harvester ants (*Pogonomyrmex salinus*). Here we present a brief summary of each of the primary threats to *L. papilliferum* for the purposes of considering new information received since 2009 and of analyzing these threats in the context of the foreseeable future, in order to reconsider whether *L. papilliferum* meets the definition of a threatened species.

In considering potential threatened species status for *Lepidium papilliferum,* it is useful to first describe what endangered species status for *L. papilliferum* would be (in danger of extinction throughout all or a significant portion of its range). *Lepidium papilliferum* will be in danger of extinction (an endangered species) when the anticipated and continued synergistic effects of increased wildfire, invasive nonnative plants, development, and other known threats affect the remaining extant *L. papilliferum* habitats at a level where the species would persist only in a small number of isolated EOs, most likely with small populations and fragmented from other extant populations, such that the remaining populations would be incapable of interchange sufficient to maintain the long-term existence of the species.

Wildfire usually results in a mosaic of burned and unburned areas, and while some EOs may persist for a time in unburned habitat "islands" within burned areas, the resulting habitat fragmentation will subject any such EOs to a high degree of vulnerability, such that they will likely not be viable over the long term. For example, wildfire often leads to a type conversion of native sagebrush-steppe to annual grassland, in which the habitat goes through successional changes resulting in grasslands dominated by invasive nonnative grasses, rather than the slickspot habitat needed by *L. papilliferum.* Therefore, although a few individuals of the species may continue to be found in burned areas, those individuals would be subject to the full impact of the threats acting on the species, and thus be highly vulnerable to local extirpation and finally extinction, as detailed in the *Summary of Factors Affecting the Species,* below.

In order to estimate when this situation (reaching the point of endangerment) might occur, we chose a threshold of 80 to 90 percent loss of or damage to the currently remaining unburned habitat. We based this threshold on the rationale that should this loss of 80 to 90 percent of current habitat happen, we conclude the remaining 10 to 20 percent of *L. papilliferum's* present habitat would be so highly fragmented that it would detrimentally affect successful insect pollination and genetic exchange, leading to a reduction in genetic fitness and genetic diversity, and a reduced ability to adapt to a changing environment. There would be little probability of recolonization of formerly occupied sites at this point, and remaining small, isolated populations would be highly vulnerable to local extirpation from a variety of threats. In addition, smaller, more isolated EOs could also exacerbate the threat of seed predation by Owyhee harvester ants, as small, isolated populations deprived of recruitment through their seed bank due to seed predation would be highly vulnerable to relatively rapid extirpation. All of these effects are further magnified by the consideration that *L. papilliferum* is a relatively local endemic, and presently persists in specialized microhabitats that have already been greatly reduced in extent (more than 50 percent of known *L. papilliferum* EOs have already been affected by wildfire). Therefore, if *L. papilliferum* should reach this point at which 80 to 90 percent of its present remaining habitat, as yet unburned, is severely impacted by the effects of wildfire, invasive nonnative plants, and other threats, we predict it would then be in danger of extinction.

We have analyzed and assessed known threats to *Lepidium papilliferum,* and used the best available information to carefully consider what effects these known threats will have on this species in the future, and over what timeframe, in order to determine what constitutes the foreseeable future for each of these known threats. In considering the foreseeable future as it relates to these threats, we considered information presented in the 2009 final listing rule

(74 FR 52014, October 8, 2009), and information we have obtained since the publication of that rule, including: (1) The historical data to identify any relevant existing trends that might allow for reliable prediction of the future effects of the identified threats; (2) any information that suggests these threats may be alleviated in the near term; and (3) how far into the future we can reliably predict that these threats will continue to affect the status of the species, recognizing that our ability to make reliable predictions into the future is limited by the quantity and quality of available data. Below, we provide a summary of our analysis of each known threat, and discuss the information regarding the timing of these threats, on which we base our conclusions regarding the application of the foreseeable future.

Altered Wildfire Regime

The current altered wildfire regime and invasive, nonnative plant species were cited in the 2009 final listing rule (74 FR 52014, October 8, 2009) as the primary cause for the decline of *Lepidium papilliferum.* The invasion of nonnative plant species, particularly annual grasses such as *Bromus tectorum* and *Taeniatherum caput-medusae* (medusahead), has contributed to increasing the amount and continuity of fine fuels across the landscape. As a result, the wildfire frequency interval has been drastically shortened from a historical range of approximately 60 to over 300 years, depending on the species of sagebrush and other site-specific characteristics, to less than 5 years in many areas of the sagebrush-steppe ecosystem at present (Wright and Bailey 1982, p. 158; Billings 1990, pp. 307–308; Whisenant 1990, p. 4; USGS 1999, *in litt.,* pp. 1–9; West and Young 2000, p. 262; Bukowski and Baker 2013, p. 557). Not only are wildfires burning far more frequently, but these wildfires tend to be larger and burn more uniformly than those that occurred historically, resulting in fewer patches of unburned vegetation, which affects the post-fire recovery of native sagebrush-steppe vegetation (Whisenant 1990, p. 4). The result of this altered wildfire regime has been the conversion of vast areas of the former sagebrush-steppe ecosystem to nonnative annual grasslands (USGS 1999, *in litt.,* pp. 1–9). Frequent wildfires promote soil erosion and sedimentation (Bunting *et al.* 2003, p. 82) in arid environments such as the sagebrush-steppe ecosystem. Increased sedimentation can result in a silt layer that is too thick for optimal *L. papilliferum* germination (Meyer and Allen 2005, pp. 6–7). Wildfire also damages biological soil crusts, which are important to the sagebrush-steppe ecosystem and slickspots where *L. papilliferum* occur because the soil crusts stabilize and protect soil surfaces from wind and water erosion, retain soil moisture, discourage annual weed growth, and fix atmospheric nitrogen (Eldridge and Greene 1994 as cited in Belnap *et al.* 2001, p. 4; Johnston 1997, pp. 8–10; Brooks and Pyke 2001, p. 4).

Several researchers have noted signs of increased habitat degradation for *Lepidium papilliferum,* most notably in terms of exotic species cover and wildfire frequency (*e.g.,* Moseley 1994, p. 23; Menke and Kaye 2006, p. 19; Colket 2008, pp. 33–34), but only recently have analyses demonstrated a statistically significant, negative relationship between the degradation of habitat quality (both within slickspot microsites and in the surrounding sagebrush-steppe matrix) and the abundance of *L. papilliferum.* Sullivan and Nations (2009, pp. 114–118, 137) found a consistent, statistically significant, negative correlation between wildfire and the abundance of *L. papilliferum* across its range. Their analysis of 5 years of Habitat Integrity and Population (HIP) monitoring data indicated that *L. papilliferum* "abundance was lower within those slickspot [sic] that had previously burned" (Sullivan and Nations 2009, p. 137), and the relationship between *L. papilliferum* abundance and fire is reported as "relatively large and statistically significant," regardless of the age of the fire or the number of past fires (Sullivan and Nations 2009, p. 118). The nature of this relationship was not affected by the number of fires that may have occurred in the past; whether only one fire had occurred or several, the association with decreased abundance of *L. papilliferum* was similar (Sullivan and Nations 2009, p. 118).

The evidence also points to an increase in the geographic extent of wildfire within the range of *Lepidium papilliferum.* Since the 1980s, 63 percent of the total *L. papilliferum* management area acreage rangewide has burned, more than double the acreage burned in the preceding three decades (from the 1950s through 1970s) (Hardy 2015, *in litt.;* note this is a different calculation than the 53 percent of the total EO area that has burned, cited below). Management areas are units containing multiple EOs in a particular geographic area with similar land management issues or administrative boundaries, as defined in the 2003 Candidate Conservation Agreement for *Lepidium papilliferum* (State of Idaho 2006, p. 9). Based on previous available information, approximately 11 percent of the total management area burned in the 1950s; 1 percent in the 1960s; 15 percent in the 1970s; 26 percent in the 1980s; 34 percent in the 1990s; and as of 2007, 11 percent in the 2000s (data based on geographic information system (GIS) fire data provided by the Bureau of Land Management (BLM) Boise and Twin Falls District; I. Ross 2008, pers. comm. and A. Webb 2008, pers. comm., as cited in Colket 2008, p. 33). Incorporating more recent data (fire data up to 2015), 21 percent of the total management area has burned since 2000 (Hardy 2016, *in litt.*). Based on the negative relationship observed between fire, *L. papilliferum,* and habitat quality as described above, we conclude that this increase in area burned translates into an increase in the number of *L. papilliferum* populations subjected to the negative effects of wildfire.

More specifically, an evaluation of *Lepidium papilliferum* EOs for which habitat information has been documented (79 of 80 EOs) demonstrates that most have experienced the effects of fire. Fifty-five of 79 EOs have been at least partially burned (14 of 16 EOs on the Boise Foothills, 30 of 42 EOs on the Snake River Plain, and 11 of 21 EOs on the Owyhee Plateau), and 75 EOs have adjacent landscapes that have at least partially burned (16 of 16 EOs on the Boise Foothills, 39 of 42 EOs on the Snake River Plain, and 20 of 21 EOs on the Owyhee Plateau) (Cole 2009, Threats Table).

In the October 8, 2009, final listing rule (74 FR 52014), we presented a geospatial data analysis that evaluated the total *Lepidium papilliferum* EO area affected by wildfire over 50 years (from 1957 to 2007). This analysis found that the perimeter of previous wildfires had encompassed approximately 11,442 ac (4,509 ha) of the total *L. papilliferum* EO area rangewide (Stoner 2009, p. 48). However, in this analysis, areas that burned twice were counted twice. When we eliminate reoccurring fires and reanalyze the data to account only for how much area burned at least once, we find that the perimeter of wildfires that had occurred over the same time period (1957–2007) encompassed approximately 7,475 ac (3,025 ha), or 47 percent of the total *L. papilliferum* EO area rangewide (Hardy 2013, *in litt.*).

At the time of the 2009 final listing rule (74 FR 52014; October 8, 2009), the total area of known EOs was estimated to be approximately 16,000 ac (6,500 ha) (this area reflects only the immediate known locations of individuals of *Lepidium papilliferum* as recognized in the IFWIS database, and does not represent the much larger geographic range of the species, which can be thought of as the "range map" or broad outer boundary encompassing all known occurrences of *L. papilliferum*). For the purposes of this rulemaking, we used GIS to calculate the area of known EOs using the most current EO data, resulting in a more accurate area equaling 15,825 ac (6,404 ha).

Since the 2009 listing, wildfires have continued to affect *Lepidium papilliferum* EOs and the surrounding habitat. Data collected from 2008 to 2014 indicates there were 25 additional fires that burned approximately 1,834 ac (742 ha) of *L. papilliferum* EOs, with approximately 864 ac (350 ha) located in areas that had not previously burned (Hardy 2015, *in litt.*). Using new fire information since 2009, and considering only impacts to new, previously unburned areas, we updated the geospatial analysis and found that over the past 59 years (1957–2015), the perimeters of 147 wildfires occurring within the known range of *L. papilliferum* have burned approximately 8,348 ac (3,378 ha), or 53 percent of the total *L. papilliferum* EO area rangewide (Hardy 2016, *in litt.*).

We recognize that caution should be used in interpreting geospatial information as it represents relatively coarse vegetation information, and may not reflect that some EOs may be located within remnant unburned islands of sagebrush habitat within fire perimeters. However, it is the best available information and provides additional cumulative evidence that increased wildfire frequency is ongoing and, as detailed in the October 8, 2009, final listing rule (74 FR 52014), is likely facilitating the continued spread of invasive plant species and Owyhee harvester ant colony expansion, all of which negatively affect *Lepidium papilliferum* and its habitat.

In addition to the geospatial information, the most recent general landscape assessment conducted during HIP transect monitoring revealed that the landscape within 500 m (0.31 mi) of 54 transects (70 percent) had lost cover of native *Artemisia tridentata* (sagebrush) due to fire (IDFG 2013, p. 9).

The understanding of impacts from climate change has not changed substantially since publication of the 2009 final listing rule (74 FR 52014, October 8, 2009). Climate change models project a likely increase in wildfire frequency within the semiarid Great Basin region inhabited by *Lepidium papilliferum.* Arid regions such as the Great Basin where *L. papilliferum* occurs are likely to become hotter and drier; fire frequency is expected to accelerate, and fires may become larger and more severe (Brown *et al.* 2004, pp. 382–383; Neilson *et al.* 2005, p. 150; Chambers and Pellant 2008, p. 31; Karl *et al.* 2009, p. 83; Miller *et al.* 2011, pp. 179–184). Although there is not yet any detectable upward trend in annual area burned, the findings of Baker (2013, pp. 15–17) suggest that current fire rotations in the Snake River Plain may be too short to allow recovery of sagebrush after fire. Baker (2013, p. 17) attributes this to the cheatgrass-fire cycle, and notes that fires on the Snake River Plain are becoming larger, due to the extensive *Bromus tectorum* invasion in that region.

Warmer temperatures and greater concentrations of atmospheric carbon dioxide create conditions favorable to the growth of *B. tectorum,* thus continuing the positive feedback cycle between the invasive annual grass and fire frequency that poses a threat that is having a significant negative effect on *L. papilliferum* (Chambers and Pellant 2008, p. 32; Karl *et al.* 2009, p. 83). Under current climate-change projections, we anticipate that future climatic conditions will favor further invasion by *B. tectorum,* that fire frequency will continue to increase, and the extent and severity of fires may increase as well. If current projections are realized, the consequences of climate change are, therefore, likely to exacerbate the existing primary threats to *L. papilliferum* of frequent wildfire and invasive nonnative plants, particularly *B. tectorum.*

As the Intergovernmental Panel on Climate Change (IPCC) projects that the changes to the global climate system in the 21st century will likely be greater than those observed in the 20th century and current trends in the climate system—increasing temperature, increasing duration and intensity of drought, decreasing snow-pack, increasing heavy precipitation events, and other extreme weather—are likely to continue through the 21st century (IPCC 2007, p. 45; IPCC 2013, p. 7), we anticipate that these effects will continue and likely increase in the future. See *Climate Change* under Factor E, in the October 8, 2009, final listing rule (74 FR 52014) for a more detailed discussion of climate change.

To determine the rate at which wildfire is impacting *Lepidium papilliferum* habitats and how far into the future we can reasonably predict the likely effects of wildfire on the species, we assessed the available data regarding the extent of *L. papilliferum* habitat that is likely to burn each year. As reported above, over the past 59 years (1957 to 2015), the perimeters of 149 wildfires occurring within the known range of *L. papilliferum* have burned approximately 8,348 ac (3,378 ha), or 53 percent of the total *L. papilliferum* EO area rangewide (Hardy 2016, *in litt.*). Thus the annual mean habitat impact due to wildfire over the past 59 years is estimated at 141 acres per year (ac/yr) (57 hectares per year (ha/yr)). As noted above, we have adjusted our analysis to avoid the potential "double counting" of areas that have burned more than once, and this rate is representative of the rate at which new (previously unburned) areas of *L. papilliferum* habitat are affected by wildfire.

At present, we estimate there are approximately 7,477 ac (3,025 ha) of *L. papilliferum* habitat remaining that have not yet been negatively impacted by fire. It is our best estimate that future rates of habitat impact will continue at least at the recently observed rate of 141 ac/yr (57 ha/yr). We believe this is a conservative estimate, as it does not account for potentially greater rates of loss due to the likely effects of climate change and increasing coverage of *Bromus tectorum.* Based on the 59 years of accurate data regarding wildfire impacts accumulated so far, we can reasonably and reliably predict that this rate will continue into the future at least until the point when no unburned habitat for the species will likely remain, which is approximately 50 years (Figure 1; USFWS 2015, *in litt.*). Thus, 50 years represents a minimum estimate of the foreseeable future for the threat of wildfire. Based on the observed rates of habitat impact due to wildfire, we can reliably predict that approximately 80 to 90 percent of the remaining *L. papilliferum* habitat not yet impacted by fire will be negatively affected by wildfire within an estimated 43 to 48 years (Figure 1). Or, to look at it another way, within an estimated 43 to 48 years, only 10 to 20 percent of currently unburned *L. papilliferum* habitat will likely remain unaffected by wildfire.

As discussed above (and in more detail below in the *Summary of Factors Affecting the Species*), when *Lepidium papilliferum* reaches this threshold, at which 80 to 90 percent of its present remaining unburned habitat has become negatively affected by wildfire and associated threats, then we conservatively conclude that the species will become in danger of extinction (will meet the definition of an endangered species). Thus, because we can reasonably predict that *L. papilliferum* is likely to become an endangered species in, at the most, approximately 43 to 48 years, we consider that projection to occur within the foreseeable future, which is at least 50 years based on extrapolation of the rate at which we expect the primary effect of wildfire will act on the species. Because of the synergistic interaction between wildfire and the invasion of nonnative plant species, by association, we assume that future colonization of *L. papilliferum* habitat by invasive nonnatives will proceed on approximately the same timetable (discussed further below). This is a conservative estimate because threats to the species other than wildfire and invasive species (*e.g.*, development) are likely to negatively affect at least some of the habitat that remains unburned within the next 50 years, reducing or eliminating the ability of that unburned habitat to support the species' life-cycle needs. Consequently, the approximation of 43 to 48 years until only 10 to 20 percent of the species' habitat remains unburned is likely an overestimate of the time it will take for the species to become endangered.

We recognize that our model (Figure 1; USFWS 2015, *in litt.*) is relatively simple, assuming, for example, that unburned habitats have similar wildfire vulnerability, and that the impacts to habitat from wildfire will continue to occur at a constant rate over time, when in reality some habitats may differ in their resistance to wildfire and the extent of area affected by wildfire will vary from year to year. However, for our purposes of developing a reliable estimate of a timeframe within which *Lepidium papilliferum* is likely to become endangered, we believe this projection uses the best scientific data available to predict the effects of wildfire on the species over time. As noted above, because of the close and synergistic association between the occurrence of wildfire and invasion by nonnative plants, followed by habitat loss and fragmentation, we believe this timeframe similarly applies to the primary threat of invasive nonnative plants and fragmentation and isolation.

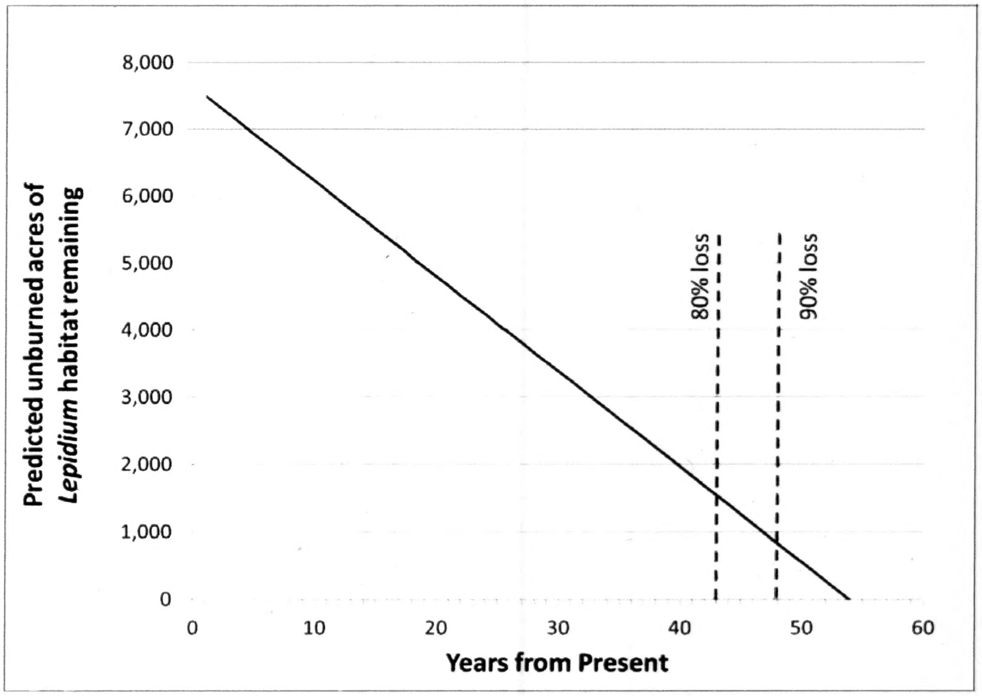

Figure 1. Rate of ongoing impacts due to wildfire in remaining *Lepidium papilliferum* habitat (USFWS 2016, *in litt.*).

In summary, wildfire effects have already impacted 53 percent of the total *Lepidium papilliferum* EO area rangewide. At the current rate of habitat impacted by wildfire, we anticipate that 80 to 90 percent of the remaining unburned *L. papilliferum* habitat will be affected by wildfire within approximately the next 43 to 48 years. Because we can reliably predict the threats of wildfire, and, by association, invasive, nonnative plant species, through at least the next 50 years, the estimated time period of 43 to 48 years in which we predict the species will become endangered is within the foreseeable future.

Invasive, Nonnative Plant Species

The rate of conversion from native sagebrush-steppe to primarily nonnative annual grasslands continues to accelerate in the Snake River Plain of southwest Idaho (Whisenant 1990, p. 4), and is closely tied to the increased frequency and shortened intervals between wildfires. The continued spread of *Bromus tectorum* throughout the range of *Lepidium papilliferum*, coupled with the lack of effective methods to control or eradicate *B. tectorum*, leads us to conclude that the extent and frequency of wildfires will continue to increase indefinitely, given the demonstrated positive feedback cycle between these factors (Whisenant 1990, p. 4; D'Antonio and Vitousek 1992, pp. 73, 75; Brooks and Pyke 2001, p. 5; Brooks *et al.* 2004, p. 678; Balch *et al.* 2013, pp. 177–179). Under current climate change projections, we also anticipate that future climatic conditions will favor further invasion by *B. tectorum,* that fire frequency will likely increase, and that the extent and severity of fires may increase as well (Brown *et al.* 2004, pp. 382–383; Neilson *et al.* 2005, p. 150; Chambers and Pellant 2008, pp. 31–32; Karl *et al.* 2009, p. 83, Bradley *et al.,* 2009 p. 5). As summarized in our 2009 final listing rule (74 FR 52014, p. 52032), if the invasion of *B. tectorum* continues at the rate witnessed over the last century, an area far in excess of the total range occupied by *L. papilliferum* could be converted to nonnative annual grasslands within the foreseeable future.

Invasive, nonnative plants have become established in *Lepidium papilliferum* habitats by spreading through natural dispersal (unseeded) or have been intentionally planted as part of revegetation projects (seeded). Invasive nonnative plants can alter multiple attributes of ecosystems, including geomorphology, wildfire regime, hydrology, microclimate, nutrient cycling, and productivity (Dukes and Mooney 2003, pp. 1–35). They can also negatively affect native plants through competitive exclusion, niche displacement, hybridization, and competition for pollinators; examples are widespread among native taxa and ecosystems (D'Antonio and Vitousek 1992, pp. 63–87; Olson 1999, p. 5; Mooney and Cleland 2001, p. 1).

Invasive nonnative plant species pose a serious and significant threat to *Lepidium papilliferum,* particularly when the synergistic effects of nonnative annual grasses and wildfire are considered. Invasive, nonnative, unseeded species that pose threats to *L. papilliferum* include the annual grasses *Bromus tectorum* and *Taeniatherum caput-medusae* that are rapidly forming monocultures across the southwestern Idaho landscape. Evidence that *B. tectorum* is likely displacing *L. papilliferum* is provided by Sullivan and Nations' (2009, p. 135) statistical analyses of *L. papilliferum* abundance and nonnative invasive plant species cover within slickspots. Working with 5 years of HIP data collected from 2004 through 2008, Sullivan and Nations found that the presence of other plants in slickspots, particularly invasive exotics such as *Bassia prostrata* (forage kochia), a seeded nonnative plant species, and *B. tectorum,* was associated with the almost complete exclusion of *L. papilliferum* from those microsites (Sullivan and Nations 2009, pp. 111–112). According to their analysis, the presence of *B. tectorum* in the surrounding plant community shows a consistently significant negative relationship with the abundance of *L. papilliferum* across all physiographic regions (Sullivan and Nations 2009, pp. 131, 137), and a significant negative relationship with *L. papilliferum* abundance within slickspots in the Snake River Plain and Boise Foothills regions (Sullivan and Nations 2009, p. 112).

Additionally, we have increasing evidence that nonnative plants are invading the slickspot microsite habitats of *Lepidium papilliferum* (Colket 2009, Table 4, pp. 37–49) and successfully outcompeting and displacing the species (Grime 1977, p. 1185; DeBolt 2002, *in litt.;* Quinney 2005, *in litt.;* Sullivan and Nations 2009, p. 109). Monitoring of HIP transects shows that *L. papilliferum*-occupied sites that were formerly dominated by native vegetation are showing relatively rapid increases in the cover of nonnative plant species (Colket 2008, pp. 1, 33; IDFG 2013, p. 11). Regarding *Bromus tectorum* in particular, vast areas of the Great Basin are already dominated by this nonnative annual grass, and projections are that far greater areas are susceptible to future invasion by this species (Pellant 1996, p. 1). In addition, most climate change models project conditions conducive to the further spread of nonnative grasses such as *B. tectorum* in the Great Basin desert area occupied by *L. papilliferum* in the decades to come (see *Climate Change* under Factor E, below).

Geospatial analyses indicate that by 2008 approximately 20 percent of the total area of all *Lepidium papilliferum* EOs rangewide was dominated by introduced invasive annual and perennial plant species (Stoner 2009, p. 81). Because this analysis only considered areas that were 'dominated' by introduced invasive species, it does not provide a comprehensive estimate of invasive species presence within the range of *L. papilliferum.* For example, similar to 2008 HIP monitoring results, which were described in the 2009 final listing rule (74 FR 52014, October 8, 2009), the 2012 results (which represent the most recent published HIP data), revealed that all 80 HIP transects monitored within 54 EOs had some nonnative, unseeded plant cover (Colket 2009, Table 4, pp. 37–49; IDFG 2013, Table 4, pp. 29–30). The 2008 (Colket 2009, Table 4, pp. 37–49) HIP monitoring results also revealed that, of the 80 HIP transects, 18 transects had some level of nonnative, seeded plant cover (similar comparisons for nonnative, seeded plant cover was not presented in the 2013 HIP monitoring report). In addition, monitoring of HIP transects rangewide indicated that nonnative plant cover is continuing to increase at a relatively rapid pace. For example, Colket (2008, pp. 1–3) reported increases in nonnative plant species cover of 5 percent or more over the span of 4 to 5 years in 28 percent of the HIP transects formerly dominated by native plant species. More recent data collected by the Idaho Department of Fish and Game (IDFG) since 2009 indicates that the number of transects with a 5 percent or more increase in nonnative cover since establishment of the transects has significantly increased from 40 transects in 2009 to 61 transects in 2011 (IDFG 2012, pp. 12–13). In the 2013 report (IDFG p. 11), this number was down slightly with 52 transects documenting a 5 percent or more increase in nonnative cover; however, it was noted that "many transects had far more than a 5% increase, and some were so heavily invaded that they were barely recognizable as slickspots."

Bradley and Mustard (2006, p. 1146) found that the best indicator for predicting future invasions of *Bromus tectorum* was the proximity to current populations of the grass. Colket (2009, pp. 37–49) reports that 52 of 80 HIP transects (65 percent) had *B. tectorum* cover of 0.5 percent or greater within slickspots in at least 1 year between 2004 and 2008; nearly 95 percent of slickspots had some *B. tectorum* present. If current proximity to *B. tectorum* is an indicator of the likelihood of future invasion by that nonnative species, then *Lepidium papilliferum* is highly vulnerable to future invasion by *B. tectorum* throughout its range. If the invasion of *B. tectorum* continues at the rate witnessed over the last century, an area far in excess of the total range occupied by *L. papilliferum* could be converted to nonnative annual grasslands in the near future. First introduced around 1889 (Mack 1981, p. 152), *B. tectorum* cover in the Great Basin is now estimated at approximately 30,000 mi^2 (80,000 km^2) (Menakis *et al.* 2003, p. 284), translating into an historical invasion rate of approximately 300 mi^2 (700 km^2) a year over 120 years. In addition, climate change models for the Great Basin region also predict climatic conditions that will favor the growth and further spread of *B. tectorum* (See *Climate Change* under Factor E in the 2009 final listing rule (74 FR 52014, October 8,

2009) for a more detailed discussion of climate change.).

Given the observed negative association between the abundance of *Lepidium papilliferum* and invasive nonnative plants both within slickspot microsites and in the surrounding plant community, the demonstrated ability of some nonnative plants to displace *L. papilliferum* from slickspots, and the recognized contribution of nonnative plants such as *Bromus tectorum* to the increased fire frequency that additionally poses a primary threat to the species, we consider invasive nonnative plants to pose a threat that is having a significant effect on *L. papilliferum*. Currently, there are no feasible means of controlling the spread of *B. tectorum* or the subsequent increases in wildfire frequency and extent once *B. tectorum* is established on a large scale (Pellant 1996, pp. 13–14; Menakis *et al.* 2003, p. 287; Pyke 2007, entire; Weltz *et al.* 2014, p. 44A). The eradication of other invasive nonnative plants poses similar management challenges, and future land management decisions will determine the degree to which seeded nonnative plants may affect *L. papilliferum*.

In summary, data show that all 80 HIP monitoring transects have some level of invasive nonnative plant species; that by 2008, 20 percent of the total area of all *Lepidium papilliferum* EOs rangewide was dominated by introduced invasive plant species; and that nonnative plant cover is continuing to increase at a relatively rapid rate. Given the synergistic relationship between wildfire and the spread of invasive nonnative plant species, such as *Bromus tectorum,* combined with the fact that broadscale eradication methods for controlling these threats have not been developed, we anticipate that 80 to 90 percent of the remaining unburned *L. papilliferum* habitat will be affected by invasive nonnative plant species, to the point where they are outcompeting *L. papilliferum,* on a timeframe similar to that of increased wildfire effects. As with the primary threat of wildfire, we can reliably predict the trend of the associated primary threat of invasive, nonnative plant species over at least the next 50 years. Therefore, this threat will also cause the species to become in danger of extinction in approximately 43 to 48 years, which is within the foreseeable future.

Planned or Proposed Development

Although the threat of development is relatively limited in geographic scope, the effect of development on *Lepidium papilliferum* can be severe, potentially resulting in the direct loss of individuals, and perhaps more importantly, the permanent loss of its unique slickspot microsite habitats. As described in the Background section of the 2009 final listing rule (74 FR 52014, October 8, 2009), *L. papilliferum* occurs primarily in specialized slickspot microsites. Slickspots and their unique edaphic and hydrological characteristics are products of the Pleistocene period, and they likely cannot be recreated on the landscape once lost. The potential, direct loss of slickspots to the effects from development, particularly those slickspots that are currently occupied by the species and provide the requisite conditions to support *L. papilliferum,* is, therefore, of great concern in terms of providing for the long-term viability of the species.

Development can also affect *Lepidium papilliferum* through indirect effects by contributing to increased habitat fragmentation, nonnative plant invasion, human-caused ignition of wildfires, and potential reductions in the population of insect pollinators. Development in sagebrush-steppe habitat is of particular concern in the Boise Foothills region, which, although relatively limited in its geographic extent, supports the highest abundance of *L. papilliferum* plants per HIP transect (Sullivan and Nations 2009, pp. 3, 103, 134). Past development has eliminated some historical *L. papilliferum* EOs (Colket *et al.* 2006, p. 4), and planned and proposed future developments threaten several occupied sites in the Snake River Plain and Boise Foothills regions (see below). Most of the recent development effects have occurred on the Snake River Plain and Boise Foothills regions, which collectively comprise approximately 83 percent of the extent of EOs; development has not been identified as an issue on the Owyhee Plateau (Stoner 2009, pp. 13–14, 19–20).

In the 2009 final listing rule (74 FR 52036, October 8, 2009), we were aware of 10 approved or proposed development projects planned for these regions (State of Idaho 2008, *in litt.* pp. 3–5), which would affect 13 out of 80 EOs (16 percent of EOs). However, many of these proposed developments and associated infrastructure projects are no longer being considered for implementation. Currently, we are aware of only three projects that could potentially affect *Lepidium papilliferum* and its habitat (Chaney, pers. comm. 2013a). The Spring Valley Planned Community (a.k.a. the M3 Development) is a 5,600-ac (2,300-ha) development in the foothills north of Eagle. Construction is planned for five phases over a 20-year period. It is expected that the development and its associated infrastructure on adjacent Federal lands will result in some effects to the species and its habitat at three EOs (EOs 52, 76, and 108) (Hardy, pers. comm. 2013). The Dry Creek Ranch Development is a 1,400-ac (570-ha) development located north of Hidden Springs in Idaho. It is proposed to be built in five phases over a 10-year period (Chaney, pers. comm. 2013b). This development appears to overlap slightly with EO 38 (a D-ranked EO). Due to the low quality of the development map, the amount of overlap is uncertain, although it appears to be a very small area relative to the size of the EO polygon (Chaney, pers. comm. 2013c). This area is currently proposed as a designated natural area of the development; therefore, direct effects associated with construction of the development are expected to be minimal.

In addition, the Gateway West Transmission Line Project, which is scheduled to be constructed in phases from 2016 through 2021, would likely affect the species and its habitat, including proposed critical habitat, in southwestern Idaho. Although a final routing of the project has not yet been determined, the Gateway West Transmission Line Project could potentially affect 5 EOs within the project footprint and a total of 11 EOs within the Action Area (defined as the right-of-way footprint and the additional 0.5-mi (0.8-km) buffer (Tetra Tech 2013, p. 64)). While conservation measures incorporated into the proposed project design are expected to avoid or minimize some adverse effects to *Lepidium papilliferum,* not all adverse effects will be avoided (USFWS, 2013 entire) and portions of the project may occur in unburned habitat.

Though these developments and associated infrastructure projects have not yet been constructed, they are at least at the proposed stage and, thus, foreseeable. Given the current information, based on approved or proposed project plans and proposed construction timelines, we anticipate that approximately 17 percent of known *Lepidium papilliferum* EOs will be affected by development within the next 20 years. This period of time represents the foreseeable future with respect to development, as this is the period of time over which we can reasonably predict development and associated infrastructure projects that will likely occur. The threat of development will have a negative effect on the species in combination with the primary threats of wildfire and invasive, nonnative plants. However, the effects of development are secondary to the effects on the species from the primary threats of an altered wildfire regime and invasive nonnative plants; thus, we do not anticipate that the threat of development alone will cause *L. papilliferum* to become an endangered species within this timeframe. However, any development that does occur in unburned habitat will contribute to shortening that timeframe.

Habitat Fragmentation and Isolation of Small Populations

Lepidium papilliferum occurs in naturally patchy microsite habitats, and the increasing degree of habitat fragmentation produced by wildfires and development threatens to isolate and fragment populations beyond the distance that the plant's insect pollinators are capable of traveling. Genetic exchange in *L. papilliferum* is achieved through either seed dispersal or insect-mediated pollination (Robertson and Ulappa 2004, pp. 1705, 1708; Stillman *et al.* 2005, pp. 1, 6–8), and plants that receive pollen from more distant sources demonstrate greater reproductive success in terms of seed production (Robertson and Ulappa 2004, pp. 1705, 1708). *Lepidium papilliferum* habitats separated by distances greater than the effective range of available pollinating insects are at a genetic disadvantage, and may become vulnerable to the effects of loss of genetic diversity (Stillman *et al.* 2005, pp. 1, 6–8) and a reduction in seed production (Robertson *et al.* 2004, p. 1705). A genetic analysis of *L. papilliferum* suggested that populations in the Snake River Plain and the Owyhee Plateau may already have reduced genetic diversity (Larson *et al.* 2006, p. 17; note the Boise Foothills were not analyzed separately in this study).

Many of the remaining occurrences of *Lepidium papilliferum,* particularly in the Snake River Plain and Boise Foothills regions, are restricted to small, remnant patches of suitable sagebrush-steppe habitat. When last surveyed, 31 EOs (37 percent) each had fewer than 50 plants (Colket *et al.* 2006, Tables 1 to 13). Many of these small remnant EOs exist within habitat that is degraded by the various threat factors previously described. Small *L. papilliferum* populations are likely persisting due to their long-lived seed bank, but the long-term risk of depletion of the seed banks for these small populations and the elimination of new genetic input make the persistence of these small populations uncertain. Providing suitable habitats and foraging habitats for the species' insect pollinators is important for maintaining *L. papilliferum* genetic diversity. Small populations are vulnerable to relatively minor environmental disturbances such as wildfire, herbicide drift, and nonnative plant invasions (Given 1994, pp. 66–67), and are subject to the loss of genetic diversity from genetic drift and inbreeding (Ellstrand and Elam 1993, pp. 217–237). Smaller populations generally have lower genetic diversity, and lower genetic diversity may in turn lead to even smaller populations by decreasing the species' ability to adapt, thereby increasing the probability of population extinction (Newman and Pilson 1997, p. 360).

Habitat fragmentation from the effects of development or wildfires has affected 62 of the 79 EOs for which habitat information is known (15 of 16 on the Boise Foothills, 35 of 42 on the Snake River Plain, and 12 of 21 on the Owyhee Plateau), and 78 EOs (all except one on the Owyhee Plateau) have fragmentation occurring within 1,600 ft (500 m) of the EOs (Cole 2009, Threats Table). Additionally, development projects are planned within the occupied range of *Lepidium papilliferum* that would contribute to further large-scale fragmentation of its habitat, potentially resulting in decreased viability of populations through decreased seed production, reduced genetic diversity, and the increased inherent vulnerability of small populations to localized extirpation (see *Development,* above).

In summary, the increasing degree of fragmentation of *Lepidium papilliferum* and its habitat is primarily produced by wildfires, loss and conversion of surrounding sagebrush-steppe habitats, and the effects of development. We can reliably predict that habitat fragmentation effects will continue at a rate similar to wildfire and other threat effects, such that 80 to 90 percent of the remaining unburned *L. papilliferum* habitat will be affected within an estimated 43 to 48 years, which is within the foreseeable future of 50 years for the primary threats of wildfire and invasive, nonnative plant species.

Owyhee Harvester Ants

In recent years, concern has emerged over the potential detrimental effects of seed predation on *Lepidium papilliferum* by the Owyhee harvester ant (Robertson and White 2009). Robertson and White reported that Owyhee harvester ants can remove up to 90 percent of *L. papilliferum* fruits and seeds, either directly from the plant or by scavenging seeds that drop to the ground (Robertson and White 2009, p. 9). A more recent study (Robertson and Crossman 2012, pp. 14–15) validated the results from Robertson and White (2009), and went further by showing that seed loss through Owyhee harvester ant predation remains high, with a median of 92 percent, even when considering total seed output for individual plants. In one of their paired samples, they found 4,861 seeds beneath the control plant and only 301 seeds beneath the treatment plant (exposed to ants), while in another they found 2,328 seeds beneath the control plant, but only 365 beneath the treatment plant. These results demonstrate that Owyhee harvester ants have the capacity to remove a large percentage of the seeds produced by *L. papilliferum,* even when thousands of seeds are produced.

Owyhee harvester ants are a native species, common in open grassy areas throughout southwest Idaho, including areas occupied by *Lepidium papilliferum.* Owyhee harvester ant colony expansion into areas adjacent to occupied slickspots, and the associated increase in seed predation, has the potential to significantly affect *L. papilliferum* recruitment and the replenishment of the seed bank, which could in turn affect the long-term viability of *L. papilliferum.* Due to the increased occurrence of wildfire and the associated replacement of sagebrush by grasses within *L. papilliferum* habitat, a study was initiated in 2010 to monitor Owyhee harvester ant colony dynamics and to document if, and at what rate, Owyhee harvester ants are increasingly colonizing areas occupied by *L. papilliferum.* In 2010, researchers recorded 843 harvester ant colonies across 15 study sites, which coincided with *L. papilliferum* EOs. Results from 2012 demonstrated that, only 2 years later, that number had increased to 956 colonies. However, data collected in 2014, following an extended period of drought in the spring and summer of 2013, showed colony numbers had declined to 878 (Robertson 2015, p. 2). Robertson concluded that the lack of consistent and substantial increases in colony numbers over the 5 years of monitoring at these sites, as well as the strong relationship between ant colony density and resources available at the sites, suggests that the sites chosen for this study were already at or near carrying capacities (Robertson 2015, p. 11). Robertson notes, however, that carrying capacity is a function of resource availability, and changes in resources likely will impact future colony recruitment and survival (Robertson 2015, p. 11).

Owyhee harvester ant research within *Lepidium papilliferum* habitat is ongoing. We lack enough data to develop a foreseeable future estimate for this threat at this time, although we expect the threat to increase as the number of ant colonies continues to grow as a result of more wildfires and the associated conversion of sagebrush to grasses.

Consideration of Conservation Measures

The threats to *Lepidium papilliferum* are ongoing and acting synergistically to negatively affect the species and its habitat, and are expected to continue into the foreseeable future. Although conservation measures to address some of these threat factors have been considered by the Service, as described in the 2009 final listing rule (74 FR 52014, October 8, 2009), effective controls on a large enough scale to address the increased frequency of wildfire and eradicate the expansive infestation of nonnative plants throughout the range of *L. papilliferum* are not currently available, nor do we anticipate that controls will become available anytime soon that are likely to be effective on a scale sufficient to prevent the species from becoming in danger of extinction in the foreseeable future.

The Conservation Agreement (CA) for *Lepidium papilliferum* between the BLM and the Service was updated in 2014 (USBLM and USFWS 2014, entire). Significant changes to that CA included allowing for livestock trailing through EOs, proposed critical habitat, or occupied habitat on existing roads or historic routes within the BLM's Four Rivers Field Office area. It also added requirements to avoid use of potentially invasive nonnative plant species such as *Bassia prostrata* (forage kochia) in emergency stabilization and rehabilitation treatments and fuel breaks within 0.8 km (1.5 mi) of EOs, as well as to require rigorous monitoring and subsequent removal of *B. prostrata* if it establishes outside of seeded areas. The 2014 CA also clarified invasive nonnative plant species control requirements associated with land use permits, leases, and rights-of-way that overlap EOs. While these changes strengthen and clarify the CA, they are not sufficient to offset the threats to the species to the point that it is not likely to become an endangered species within the foreseeable future.

In addition to those conservation measures evaluated in the 2009 final listing rule (74 FR 52014, October 8, 2009) and those mentioned above, we considered a relatively new conservation measure. Rangeland Fire Protection Associations (RFPAs) are currently being established in some parts of southern Idaho, where important habitat for greater sage-grouse (*Centrocercus urophasianus*) (''sage-grouse'') occurs. These RFPAs are designed to provide ranchers and landowners in rural areas with the necessary tools and training to allow them to assist with wildfire prevention and respond quickly to wildfire. One of these RFPAs, the Three Creek RFPA, has been established within the *Lepidium papilliferum* Owyhee Plateau physiographic region, where both *L. papilliferum* and sage-grouse co-occur. Benefits from first response to wildland fires that are realized to sage-grouse within this RFPA may also extend to *L. papilliferum* habitat in that area. The Mountain Home RFPA, which was recently expanded in 2015 to include additional *L. papilliferum* EOs, also covers a portion of *L. papilliferum* occupied habitat within the Snake River Plain physiographic region.

Idaho Code Section 38–104 was amended during the 2013 legislative session to clarify the requirements and process for the establishment of the RFPAs (State Board of Land Commissioners 2013, *in litt.*). Applicants that meet the requirements of an RFPA enter into a Master Agreement with the State, which provides them with the legal authority to detect, prevent, and suppress fires in the RFPA boundaries. RFPAs also require a Cooperative Fire Protection Agreement between the individual RFPA and the appropriate Federal agency, which provides the RFPAs the authority to take action on Federal land (Houston 2013, pers. comm.; Glazier 2013, pers. comm.).

The Service acknowledges that RFPAs are a positive conservation step for sagebrush-steppe habitat, and we commend these efforts to protect habitats against wildfires in those areas where RFPAs have been designated; the Service has provided funding to help support RFPAs. One of the primary benefits of the RFPAs, as identified by the Idaho Department of Lands, is the protection of greater sage-grouse habitat. Consequently, most of the currently designated RFPAs are associated with greater sage-grouse habitat, and only approximately 34 percent of *Lepidium papilliferum* EOs are currently located inside of any designated RFPA boundaries. While benefits from first response to wildland fires within sage-grouse habitats may also extend to *L. papilliferum* habitat in those areas where the RFPA boundaries overlap (34 percent), a majority (66 percent) of currently occupied *L. papilliferum* habitat does not directly benefit from the sage-grouse-associated wildfire protection measures of the RFPAs. Furthermore, RFPAs within the range of *L. papilliferum* have been in effect for only 1 to 3 years and, as such, have not yet demonstrated their ability to address the increased frequency or extent of wildfire across the range of *L. papilliferum*.

Although 34 percent of *Lepidium papilliferum* habitat is within RFPA boundaries, these areas are at a high risk of large catastrophic wildfires based on ecological conditions (Chambers *et al.* 2014, entire). This higher risk was analyzed in the resilience and resistance (R&R) matrix developed by the Western Association of Fish and Wildlife Agencies (WAFWA), in which they classified different ecological soil and moisture regimes into categories (low, moderate, and high) of resilience to disturbance and resistance to invasion by annual grasses (Chambers *et al.* 2014, entire). Of the areas occupied by *L. papilliferum,* 99 percent occur within areas classified as low R&R; these low R&R areas tend to be prone to invasion by cheatgrass and are at a higher risk of large catastrophic wildfires, thus the low R&R of these areas is a challenge to wildfire management and post-fire restoration.

In addition, RFPAs do not address the threat from existing invasive nonnative plant species, the second of the two primary threats identified for the species, and the conservation need for sagebrush-steppe habitat restoration. Our analysis of the conditions for *Lepidium papilliferum* over the foreseeable future takes into account the synergistic and cumulative effects of increased wildfire, invasive nonnative plants, development, and other threat factors that will affect the remaining *L. papilliferum* habitats.

Effective management of wildfire as a threat is often dependent on the timeliness of initial response efforts; therefore, while RFPAs have not yet shown to be sufficiently effective to offset the threats to the species to the point that it is not likely to become an endangered species within the foreseeable future, we view their formation as a positive conservation step for sagebrush-steppe habitat. We continue to support expanding and increasing the capacity of RFPAs, and encourage greater wildfire protection measures and sagebrush-steppe restoration in other areas with *L. papilliferum* habitats. However, the combination of adequately addressing the two primary threats of wildfires and invasive nonnative plant species will be necessary for long-term conservation of *L. papilliferum.*

Summary of Factors Affecting the Species

The current status of *Lepidium papilliferum* reflects the past effects from the threats described above that have already affected or degraded more than 50 percent of the species' unique habitats, as well as the continued and ongoing vulnerability of the species' slickspot habitats to these same threats. Because we do not see strong evidence of a steep negative population trend for the species (consistent with what we described in our 2009 final listing rule (74 FR 52051, October 8, 2009)), we believe that *L. papilliferum* is not in immediate danger of extinction. We do, however, conclude that *L. papilliferum* is likely to become in danger of extinction in the foreseeable future, based on our assessment of that period of time over which we can reasonably rely on predictions regarding the threats to the species. Our analysis has led us to conclude that future effects from the synergistic and cumulative effects of increased wildfire, invasive nonnative plants, development, and other threat factors, including climate change, will affect the remaining *L. papilliferum* habitats such that the species would persist in only a small number of isolated EOs, with 80 to 90 percent of its remaining unburned habitat impacted by these threats, and most likely with small populations fragmented and isolated from other remnant populations. At the point at which these conditions are met, we would consider the species to then be in danger of extinction.

Given the wildfire history that has affected approximately 53 percent of the *L. papilliferum* habitat over the last 59 years (1957–2015), combined with the ongoing, expansive infestation of invasive nonnative plants across the species' range, and the fact that no broad-scale *Bromus tectorum* eradication methods or effective means for controlling the altered wildfire regime across the range of *L. papilliferum* have been developed, these threats to *L. papilliferum* can reasonably be anticipated to continue for at least 50 years, and perhaps indefinitely. This information (in concert with the observed negative association between these ongoing and persistent threats and the species' distribution and abundance throughout its range, along with reasonable predictions about future conditions) leads us to the conclusion that, at the current and anticipated rate of future habitat effects, *L. papilliferum* is likely to become in danger of extinction within the next 43 to 48 years, which is within the foreseeable future (the time period of at least 50 years over which we can reliably predict the primary threat factors will continue to act upon the species).

Summary of Changes From the Proposed Reconsideration of the Final Rule

Based upon our review of the public comments and new relevant information that has become available since the publication of our proposed reconsideration of the final rule (79 FR 8416; February 12, 2014), we have reevaluated and made changes to the content of that document as appropriate. Other than minor clarifications and incorporation of additional information on the species' biology and populations, this determination differs from the proposed reconsideration document in the following ways:

(1) The State of Idaho disagreed with the Service's assertion that RFPAs have not yet demonstrated their ability to address the increased frequency of wildfire across the range of *Lepidium papilliferum.* The State commented that increased fire response and suppression in *L. papilliferum* habitat would undoubtedly alter the point at which the plant would become endangered, and suggested our determination was no longer valid because 2013 RFPA data was not factored into the Service's foreseeable future analysis.

To address the State's concern, we re-calculated our foreseeable future estimate (the rate at which wildfire is impacting *Lepidium papilliferum* habitats), to include wildfire data from 2013 to 2015. Therefore, instead of using the past 56 years of data (1957 to 2012), we used the past 59 years of data (1957 to 2015) to assess how far into the future we can reasonably predict the likely effects of wildfire on the species. In the proposed reconsideration of the final rule, we stated that we used 55 years of wildfire data based on a time period between 1957 and 2012; we added the number of years incorrectly and have corrected the number for this time period to be 56 years.

In our proposed reconsideration of the final rule (79 FR 8416; February 12, 2014), we reported that, using the past 56 years of data, the perimeters of 126 wildfires occurring within the known range of *Lepidium papilliferum* burned approximately 8,324 ac (3,369 ha), or 53 percent of the total *L. papilliferum* EO area rangewide (Hardy 2013, *in litt.*). As reported in this final rule, over the past 59 years (1957 to 2015), the perimeters of 149 wildfires occurring within the known range of *L. papilliferum* have burned approximately 8,348 ac (3,378 ha), which is 53 percent of the total *L. papilliferum* EO area rangewide (Hardy 2016, *in litt.*). Thus, the annual mean habitat impact due to wildfire changed from 150 acres per year (ac/yr) (61 ha/yr) over a 56-year time period to 141 acres per year (ac/yr) (57 ha/yr) over the past 59 years.

To be consistent, we also used the latest IFWIS EO data (January 2015) to calculate the *Lepidium papilliferum* habitat remaining that has not yet been negatively impacted by wildfire. In our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), we reported that there were 87 EOs currently identified in the IFWIS database (compared to 80 reported in 2009). However, we should have reported that there were 88 total EOs. Since the proposed reconsideration document was published, 3 more EOs have been identified in the IFWIS database, bringing the total to 91 extant *L. papilliferum* EOs. Using the latest EO data changed our estimate from approximately 7,567 ac (3,064 ha) to 7,479 ac (3,026 ha) of *Lepidium papilliferum* habitat remaining that has not yet been affected by wildfire.

Based on the observed rates of habitat impact due to wildfire using this longer time range and updated EO information, we can reliably predict that approximately 80 to 90 percent of the remaining *Lepidium papilliferum* habitat not yet impacted by wildfire will be affected within approximately the next 43 to 48 years, which is a change and refinement from the estimate of 36 to 47 years in the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014).

Considering the most recent wildfire data (2013 to 2015), as requested by the State, did not alter our conclusion that *Lepidium papilliferum* is likely to become in danger of extinction within the foreseeable future. Therefore, we still conclude that the RFPAs have not yet demonstrated their ability to address the increased frequency of wildfire throughout the range of *L. papilliferum.* In addition, RFPAs do not address the threat from existing invasive nonnative plant species, the second of the two primary threats identified for the species, and the conservation need for sagebrush-steppe habitat restoration.

Based on the changes discussed above, we refined our graph in Figure 1 to reflect this new information.

(2) We received comments regarding our use of a 5-year dataset that resulted in the upper-bound calculation of 170 ac (69 ha) of habitat burned per year presented in the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014). Some commenters stated that this short

timeframe is arbitrary, as it is based on a small sample size, and suggested that it should not be relied upon. We agree with the commenters that our 5-year estimate is too short a timeframe to accurately reflect the average impact of wildfire. Therefore, we removed this upper-bound estimate from this final rule. However, we believe our long-term estimate of an average future rate of 141 ac (57 ha) of habitat burned per year (based on the last 59 years) is a reliable and reasonable estimate and represents the best available data.

(3) In the Background and New Information section of the preamble, we corrected our HIP plant count numbers and some HIP data analysis based on new information received.

(4) In the Factors Affecting the Species section of the preamble, we updated information in the *Owyhee Harvester Ant* section based on new research results received.

(5) In the Factors Affecting the Species section of the preamble, *Altered Wildfire Regime* section, we updated the HIP transect data information to reflect the most recent results of the 2012 HIP monitoring. Based on a public comment, we also updated this section to include more recent climate change information, as well as more recently described fire-return intervals.

(6) In response to a comment from the State of Idaho, we expanded our discussion in the Consideration of Conservation Measures section of the preamble to include additional information regarding RFPAs.

Summary of Comments and Recommendations

In our proposed reconsideration of the final rule published on February 12, 2014 (79 FR 8416), and in the document reopening the comment period (April 21, 2014, 79 FR 22076), we requested that all interested parties submit written comments on our proposed interpretation of the foreseeable future and reinstatement of threatened status for *Lepidium papilliferum.* We contacted appropriate Federal and State agencies, scientific experts and organizations, and other interested parties, and invited them to comment on our proposed reconsideration of the final rule. We did not receive any requests for a public hearing. During these comment periods we received 11 comment letters. We appreciate all public comments submitted and their contributions to the improvement of the content and accuracy of this document.

We received several comments related to the prior listing decision published on October 8, 2009, such as comments regarding the taxonomy of this species, population trend, and our analysis of threats as described in the 2009 final listing rule (74 FR 52014). We also received comments related to other issues that are outside the scope of this rulemaking, such as comments related to the National Environmental Policy Act. For the purposes of this rulemaking, we considered only comments directly relevant to the proposed reconsideration of the final rule for *Lepidium papilliferum,* as published on February 12, 2014 (79 FR 8416). Comments that did not provide new information or that were related to issues outside the scope of this rulemaking are not addressed here.

All substantive information provided has either been incorporated directly into this final rule or addressed below.

Federal Agency Comments

We did not receive any comments from Federal agencies.

Comments From the State of Idaho

Comments received from the State regarding our proposed reconsideration of the final rule for *Lepidium papilliferum* (79 FR 8416, February 12, 2014) are addressed below, and also in a written response to the State of Idaho per section 4(i) of the Act that states, "the Secretary shall submit to the State agency a written justification for his failure to adopt regulations consistent with the agency's comments or petition."

(1) Comment: The State pointed out that in the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), the foreseeable future is determined to be "at least 50 years"; however, the phrase "at least" is not quantifiable nor does it provide any sideboards for determining what number of years after 50 would be considered foreseeable. The State argued that, for the purpose of analyzing whether *Lepidium papilliferum's* risk of endangerment is within the foreseeable future, 50 years is the threshold since "at least" creates an equivocal timeframe.

Our Response: We consider the foreseeable future to be that period of time within which we can make a reasonable prediction about the future status of the species, based on the nature of the threats, how the species is affected by those threats, and how those relevant threats operate over time. In this case, one of the primary threats is wildfire, and we can reasonably predict how that threat will operate over time based on 59 years of fire data and the observed effects of wildfire on *Lepidium papilliferum.* We defined the timeframe for when *L. papilliferum* is likely to become in danger of extinction (endangered) as that point in the future when only 10 to 20 percent of its remaining, as-yet-unburned habitat persists unaffected by wildfire, because we conclude that under those conditions the remaining habitat will be too small and fragmented to provide for the persistence of the species, such that the species will become in danger of extinction at that time. Because *L. papilliferum* has not yet reached that point, we can conclude that it is not currently in danger of extinction (*i.e.,* not endangered). However, based on the best available data, we have reasonably projected that the species is likely to reach that point (when it will *become* in danger of extinction) in approximately 43 to 48 years.

Because we can reasonably predict the time period in the future at which the species is likely to become endangered (as opposed to merely speculating as to when it might occur), that point in time is by definition within the foreseeable future. In turn, because we can reasonably and reliably predict that this rate will then continue into the future at least until the point when no unburned habitat for the species will likely remain, which is approximately 54 years (Figure 1; USFWS 2016, in litt.), 50 years represents a reasonable minimum estimate of the foreseeable future. This led to our description of the timeframe for the foreseeable future being "at least" 50 years (simply rounding down from 54 years). Perhaps a better way of explaining it is that we can reasonably predict the transition from threatened to endangered status to occur within the next 50 years. The number of years beyond 50 that would be considered foreseeable is a moot point, since we have reasonably concluded that *L. papilliferum* will become in danger of extinction prior to that time. We used the term "at least" in an attempt to communicate the uncertainty around the timeframe of 50 years, as we believe that setting a single endpoint beyond that timeframe implies a degree of precision in defining the foreseeable future that simply cannot be achieved with the best available data.

(2) Comment: The State suggested that the Service did not follow the District Court's guidance on appropriately defining *Lepidium papilliferum's* foreseeable future, citing the following guidance from the Court: "remand may very well require additional fact-finding; the Service may decide that an expert panel needs to be reconvened to offer an opinion on what constitutes foreseeable future. . .." The State commented that the Service chose to forego convening an expert panel and

unilaterally concluded the foreseeable future to be at least 50 years, and further predicted that the species would likely become endangered in the next 36 to 47 years based on current and historical trend data related to the major threats facing *L. papilliferum,* namely wildfire. While the State agreed that this approach constitutes a valid viewpoint, they felt that prior agency precedent related to *L. papilliferum* indicates that this represents only one opinion in a field where experts' opinions have varied greatly. They recommended the Service exercise its discretionary authority to extend the proposed listing determination by 6 months to convene a diverse panel of experts in order to more accurately assess when the scientific community believes the species is likely to become endangered. Several other commenters recommended that, in order to properly analyze the impacts of beneficial projects, such as Rangeland Fire Protection Associations (RFPAs), the Paradigm Fuel Break Project, and State plans aimed at fire prevention (such as the Idaho and Southern Montana Greater Sage-Grouse Draft Land Use Plan Amendment and Environmental Impact Statement), we should convene an expert panel, including fire and fuels specialists, to determine future wildfire risk to *L. papilliferum* and analyze the potential benefits of these activities on the longevity of the species, and then reassess the foreseeable future.

Our Response: In accordance with section 4(b)(1)(A) of the Act, our determination is based solely on the best scientific and commercial data available. We recognize the potential value in convening expert panels to assist in our status reviews, especially for issues where significant uncertainty exists. We did not find that to be the situation here. We based our definition of the foreseeable future specific to *Lepidium papilliferum* on the best scientific data available to us regarding the observed rate at which the primary threats are acting on the species. This is a quantitative estimate and not a qualitative opinion as the State suggests. With the availability of this quantitative estimate to frame the foreseeable future, we did not find that convening an expert panel for the purpose of soliciting qualitative opinions was necessary. Please also see our discussion of the outcome of earlier expert panels under "Foreseeable Future," above.

(3) Comment: The State and the Idaho State Department of Agriculture (ISDA) commented that the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) does not adequately analyze the RFPAs. The State suggested that a large portion of *Lepidium papilliferum* habitat exists on rangeland currently covered by RFPAs. The State also disagreed with the Service's assertion that RFPAs have not yet demonstrated their ability to address the increased frequency of wildfire within the range of *L. papilliferum.* They asserted that, after just 2 years in existence, the RFPAs have proven successful, offering that the Three Creek and Mountain Home RFPAs, both established within *L. papilliferum* habitat, provided initial attack and/or assistance on numerous wildfires during the 2013 wildfire season. They added that, on many of these fires, the quick actions taken by the RFPAs directly prevented additional acres from burning, which likely would have included occurrences of *L. papilliferum.*

The State acknowledged that it is impossible to quantify the number of acres saved due to the implementation of RFPAs, but felt the information from 2013 illustrates the tangible progress the RFPAs are making across their range. They contended that, since 2013 RFPA data was not factored into the Service's foreseeable future analysis, the determination is no longer valid, arguing that increased fire response and suppression in *L. papilliferum* habitat would undoubtedly alter the point at which the plant would become endangered. They added that, in order to adequately support this determination, the Service would have to provide information describing how recent wildfire reduction measures within the species' range would not affect *L. papilliferum's* timeline for becoming endangered. Several additional commenters also commented that the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) did not adequately analyze the RFPAs and the associated positive effects they have had in reducing the size of wildfires in *L. papilliferum* habitats. One of these commenters stated that currently there are 5 RFPAs comprising more than 250 private citizens who are properly trained and equipped to provide initial attack on over 4 million acres of private, State, and Federal land and 6 more RFPAs that are in the process of formation and training to be ready for the 2015 wildfire season.

Our Response: The Service acknowledges that RFPAs are a positive conservation step for sagebrush-steppe habitat, and we commend these efforts to protect habitats against wildfires in those areas where RFPAs have been designated. One of the primary benefits of the RFPAs, as identified by the Idaho Department of Lands, is for the protection of greater sage-grouse habitat. Consequently, most of the currently designated RFPAs are associated with greater sage-grouse habitat. However, only approximately 34 percent of *L. papilliferum* EOs are currently located inside of any designated RFPA boundaries. While benefits from first response to wildland fires within sage-grouse habitats may also extend to *L. papilliferum* habitat in those areas where the RFPA boundaries overlap (34 percent), a majority (66 percent) of currently occupied *L. papilliferum* habitat does not directly benefit from the sage-grouse-associated wildfire protection measures of the RFPAs. Furthermore, RFPAs within the range of *L. papilliferum* have only been in effect for 1 to 3 years and, as such, have not yet demonstrated their ability to address the increased frequency or extent of wildfire across the range of *Lepidium papilliferum.*

Although 34 percent of *Lepidium papilliferum* habitat is within RFPA boundaries, these areas are at a high risk of large catastrophic wildfires based on ecological conditions (Chambers *et al.* 2014, entire). This higher risk was analyzed in the R&R matrix developed by the WAFWA, in which they classified different ecological soil and moisture regimes into categories (low, moderate, and high) of resilience to disturbance and resistance to invasion by annual grasses (Chambers *et al.* 2014, entire). Of the areas occupied by *L. papilliferum,* 99 percent occur within areas classified as low R&R; these low R&R areas tend to be prone to invasion by cheatgrass and are at a higher risk of large catastrophic wildfires, thus the low R&R of these areas is a challenge to wildfire management, particularly for catastrophic wildfires.

Further, as the State pointed out, it is impossible to quantify the number of acres saved due to implementation of the RFPAs. We did consider, in response to the State's request, whether it was appropriate to evaluate the potential effectiveness of RFPAs based on wildfire data since their date of establishment, which varies from 2013 to 2015. However, relying on 1 to 3 years of wildfire data (the short duration of time that RFPAs have been in effect) is too small a sample size to determine if there is a long-term change in the rate of number of acres burned as a result of RFPAs.

However, we have recalculated the foreseeable future by adding 2013 thru 2015 wildfire data and have updated this information in the Factors Affecting the Species section of this final rule. Based on the observed rates of habitat impact due to wildfire using this longer time range and updated EO information, we can reliably predict that approximately 80 to 90 percent of the remaining *Lepidium papilliferum* habitat not yet impacted by wildfire will be affected within an estimated 43 to 48 years, which is a change from the estimate of 36 to 47 years in our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014). Therefore, considering the most recent wildfire data (2013 to 2015), as requested by the State, did not alter our conclusion that *L. papilliferum* is likely to become in danger of extinction within the foreseeable future.

In addition, our analysis of the foreseeable future takes into account the synergistic and cumulative effects of increased wildfire, invasive nonnative plants, development, and other threat factors that will affect the remaining *L. papilliferum* habitats. While RFPAs have the potential to influence the overall effect of wildfires, they do not address the threat from existing invasive nonnative plant species, the second of two primary threats identified for the species, or the conservation need for sagebrush-steppe habitat restoration.

Therefore, while we view the formation of RFPAs as a positive conservation step for sagebrush-steppe habitat, RFPAs have not yet shown to be sufficiently effective to offset the threats to the species to the point that it is not likely to become an endangered species within the foreseeable future.

(4) Comment: The State and the ISDA commented that the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) did not adequately address the benefits derived from the Paradigm Fuel Break Project. The State cited one of the objectives of the Paradigm Project, to "[p]rotect existing native shrub habitat for slickspot peppergrass and greater sage-grouse, that would reduce the likelihood of large-scale wildfire." They contended that, while a record of decision for the Paradigm Project has not been issued, the project still must be considered by the Service when analyzing the future threat from wildfire since this project will have an appreciable effect on the number and magnitude of fires within the project area and associated *Lepidium papilliferum* habitat. Likewise, seven additional commenters questioned why we did not analyze the effects the Paradigm Fuel Break Project will have on the foreseeable future for *L. papilliferum.* Five of these commenters suggested that the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) did not adequately address the benefits derived from the Paradigm Project. Several of these commenters stated that this project will slow the spread of wildfires and assist in fire suppression efforts. Several commenters thought this would greatly extend or shift the foreseeable future or entirely preclude the need to consider ESA listing for the species. One commenter stated that it is not unreasonable to expect this project will be implemented within the Service's 50-year timeline. Conversely, two of the commenters stated that this project will negatively impact *L. papilliferum* by introducing invasive nonnative plants, such as *Bassia prostrata,* as fuel breaks across a large amount of *L. papilliferum* habitat. One of these commenters stated that existing *B. prostrata* seedings have already invaded *L. papilliferum* habitat. The other added that, given the competitiveness of *B. prostrata* and a lack of proper planning, the *L. papilliferum* habitat near fuel breaks will soon be invaded by *B. prostrata,* and *L. papilliferum* will become extinct.

Our Response: We are aware of the potential future long-term benefits that may occur associated with compartmentalization of future wildfires in this area. We also acknowledge, as discussed in detail under Factor A of the 2009 final listing rule (74 FR 52037–52040, October 8, 2009), the risks associated with seeded nonnative invasive plant species like *Bassia prostrata,* in areas that support *Lepidium papilliferum.* As such, we continue to encourage our partners to minimize any potential adverse impacts of proposed fuel break projects in the vicinity of *L. papilliferum* habitat. For example, guidance on how to avoid or minimize potential effects of fuels management projects on *L. papilliferum* and its habitat has been provided in the 2014 Conservation Agreement (CA) for *L. papilliferum* between BLM and the Service, and we anticipate the BLM will adhere to the CA. Subsequent to the publication of our proposed reconsideration of the final rule, the Service coordinated with the BLM regarding strategies to avoid or minimize potential effects of the proposed Paradigm Project on *L. papilliferum* prior to the BLM signing the Decision Record for this project on April 24, 2015. However, the Paradigm Fuel Break Project only encompasses about 18 percent of the total area of *L. papilliferum* habitat rangewide.

In addition, the Service is not aware of any long-term data regarding suppression effectiveness of fuel breaks in areas of low R&R, which is where more than 99 percent of *L. papilleriferum* occurs. Moreover, our analysis of foreseeable future takes into account the synergistic and cumulative effects of increased wildfire, invasive nonnative plants, development, and other threat factors that will affect the remaining *L. papilliferum* habitats. While the Paradigm Project has the potential to influence the overall effect of wildfires within a limited area of *L. papilliferum* habitat, it does not currently address the threat from existing invasive nonnative plant species, one of two primary threats identified for the species, or the conservation need for sagebrush-steppe habitat restoration. Considering all of these factors, it is unknown if the Paradigm Project will significantly alter the rangewide foreseeability of threats to this species.

(5) Comment: The State and the ISDA commented that the Service did not consider the benefits to *Lepidium papilliferum* associated with recent sage-grouse planning efforts in Idaho. They pointed out that, as with *L. papilliferum,* the primary threats to sage-grouse habitat are wildfires and invasive species, and the Idaho and Southwest Montana Subregional sage-grouse planning effort includes a wildfire management component that focuses efforts on fire prevention, suppression, and habitat restoration. The State suggested that some of the *L. papilliferum* habitat will incidentally benefit from the protections afforded to sage-grouse through this strategy, and given the overlap of sage-grouse and *L. papilliferum* habitat, these planning efforts would have a positive influence on *L. papilliferum* and its habitat. Five additional commenters also had similar comments. Several commenters questioned whether the Service has taken into consideration other State plans aimed at fire prevention and habitat preservation, like the Idaho and Southwestern Montana Greater Sage-Grouse Draft Land Use Plan Amendment and Environmental Impact Statement. One commenter stated that the two primary threats to *L. papilliferum* are also the primary threats to the greater sage-grouse and the proposed reconsideration of the final rule does not consider any of the organizations and tools that have been created to protect against those threats, such as the amendments to BLM Resource Management Plans (RMPs). This commenter argued that factoring all of these benefits in will alter the foreseeable future.

Our Response: The Service recognizes the future potential benefits to sagebrush-steppe habitats associated with the BLM's efforts to conserve greater sage-grouse through amendment of existing land use plans, including increased measures to limit wildfire impacts to sagebrush steppe habitats and revegetation efforts. We considered several greater sage-grouse conservation efforts that may provide benefits to *Lepidium papilliferum* habitat, including the land use plan amendments, the Fire and Invasives Team (FIAT) planning areas, and activities identified in response to Secretarial Order (SO) 3336.

Less than 21 percent of the known area of *Lepidium papilliferum* occurrences overlap with greater sage-grouse habitats where the BLM will implement land use plan amendment conservation measures (including habitat restoration and fire suppression actions). Furthermore, conservation measures within the BLM land use plan amendment for sage-grouse are largely directed at Priority and Important Habitat Management Areas. Only 17 percent of the known *L. papilliferum* occurrences overlap with designated Important Habitat Management Areas (IHMA), 4 percent occur in General Habitat Management Areas, and none of the remaining 83 percent of known *L. papilliferum* occurrences are located in Priority Habitat Management Areas.

Although *Lepidium papilliferum* does occur in areas designated as IHMA, the actions identified in the land use management plan amendments were prioritized by the FIAT and are focused on providing benefits to sage-grouse. Projects were prioritized to address breeding habitat for sage-grouse within areas that are the most resistant and resilient to wildfire. Only a very small area, approximately 1 percent of *Lepidium papilliferum* EO acres, occurs in prioritized areas. The likelihood of projects occurring in *L. papilliferum* EOs is very low and, therefore, unlikely to provide a significant benefit to the species.

The SO 3336 commits to large-scale conservation to address fire and invasive nonnative plants; however, the initial focus is on sagebrush ecosystems and sage-grouse habitat. While the SO includes commitments to ensure restoration will be initiated following wildfire, since projects are prioritized relying on FIAT prioritization, areas where *Lepidium papilliferum* occurs have not been identified as a priority.

Differences exist in the vulnerability of sage-grouse and *Lepidium papilliferum* to landscape-level threats such as wildfire and invasive nonnative plants. Greater sage-grouse are distributed across a much wider range than *L. papilliferum* and occur in areas of varying resilience to disturbance and resistance to invasion by annual grasses. Due to the wider range and variety of habitat conditions, sage-grouse rangewide are more capable of absorbing the impact of large wildfires. Conversely, *L. papilliferum* has a narrow range, is found overwhelmingly (99 percent of occurrences) in areas of low resilience to disturbance and resistance to invasion by annual grasses, and could be heavily impacted by a single catastrophic wildfire such as the 2015 Soda Fire in southwestern Idaho and Eastern Oregon, which burned 283,000 ac (114,000 ha) (National Interagency Fire Center 2015).

Further, sage-grouse conservation efforts have recognized the difficulty in preventing wildfire and controlling invasive nonnative plants in areas with low R&R (where 99 percent of *Lepidium papilliferum* occurs) and have thus focused on implementing fire prevention and restoration in areas within habitats with higher R&R.

As such, we do not anticipate the land use plan amendments will significantly alter the rangewide foreseeability of threats to *Lepidium papilliferum*. Based on our evaluation of the present threats to *L. papilliferum*, we conclude that the species is likely to become in danger of extinction within the foreseeable future after accounting for the Federal land use plan amendments to the RMPs.

(6) Comment: The State asserted that the aforementioned current and future conservation efforts in Idaho, along with the plant's inherent lack of predictability, are sufficient to preclude a listing under the ESA. They added that State management of slickspot peppergrass is proven to be just as effective as Federal management when dealing with ubiquitous threats like wildfire and invasive nonnative plant species. They requested the Service withdraw the proposal to reinstate the listing of *Lepidium papilliferum* as threatened under the ESA.

Our Response: In regard to the State's comment about current and future conservation efforts, please see our responses to comments 3, 4, and 5, above. Past population trend data were not used in making the listing decision for *Lepidium papilliferum* as "it would be inappropriate to rely on this model to predict any future population trajectory for *L. papilliferum*" (see pp. 52022–52025 of the final listing rule, 74 FR 52014; October 8, 2009). We acknowledge that above-ground numbers of *L. papilliferum* individuals can fluctuate widely from one year to the next; however, as stated in our 2009 final listing rule, we have information indicating a statistically significant negative association between *L. papilliferum* abundance and wildfire, and between *L. papilliferum* abundance and cover of *Bromus tectorum* in the surrounding plant community. Our analysis of the foreseeable future for the purposes of assessing the status of *L. papilliferum* relies on the foreseeability of the relevant threats to the species over time, and the reasonably anticipated effects of those threats on the species over time. As described here, we anticipate the continuation or increase of all of the significant threats to *L. papilliferum* into the foreseeable future, even after accounting for ongoing and planned conservation efforts, and we find that the best available scientific data indicate that the negative consequences of these threats on the species will likewise continue or increase. As described above, population declines and habitat degradation will likely continue in the foreseeable future to the point at which *L. papilliferum* will become in danger of extinction. Regarding the comment that State management of *L. papilliferum* is just as effective as Federal management, we acknowledge (as we did in the 2009 listing rule (74 FR 52014, October 8, 2009)) the efforts of the State and other entities to implement conservation measures for the species. However, the best available information leads us to conclude that currently available management tools are not capable of effectively reducing or ameliorating the primary threats across the range of the species to the point where it does not require listing under the ESA. Please refer to the Evaluation of Conservation Efforts section of the 2009 final listing rule (74 FR 52014, October 8, 2009) for a more detailed discussion of our previous evaluation of conservation efforts being made by the State of Idaho and other entities to protect *L. papilliferum*.

(7) Comment: The State commented that, in order to support the threatened determination, the Service extrapolates wildfire data from the previous half-century in order to predict future wildfire trends. The State expressed that it is overly simplistic to base a listing on the assumption that, because on average 150 acres of habitat have burned each year for the past 50 years, 150 acres will continue to burn each year in the future, particularly when considering the proactive measures mentioned in the previous comments above.

Our Response: We recognize that our model (Figure 1; USFWS 2015, *in litt.*) is relatively simple, assuming, for example, that unburned habitats have similar wildfire vulnerability, and that the impacts to habitat from wildfire will continue to occur at a constant rate over time, when in reality some habitats may differ in their resistance to wildfire and the extent of area affected by wildfire will vary from year to year. However, for our purposes of developing a reliable estimate of a timeframe within which *Lepidium papilliferum* is likely to become endangered, we believe this projection makes reasonable use of the best scientific data available to predict the effects of wildfire on the species over time. Regarding the reference to the conservation measures, please refer to responses to Comments 3–6. In addition, we anticipate that future climatic conditions will favor further invasion by *B. tectorum,* that fire frequency will continue to increase, and the extent and severity of fires may increase as well; given these considerations, we conclude that our estimate is relatively conservative.

(8) Comment: The State commented that the Service's use of a 5-year dataset that resulted in the 170 acres per year calculation is unreliable and unreasonable because it is based on a small sample size, during which Idaho experienced one of the worst fire seasons on record (2012). They argued that using such a short window of years to predict future trends is completely arbitrary and should not be relied upon. Another commenter also felt that our burn rate calculation method for determining the foreseeable future is too low and also flawed because we assume a uniform fire rate based on an arbitrary 5-year period of time. The commenter stated that the Service cannot "reasonably and reliably predict that this rate will continue," given current understanding of accelerating climate change threats and effects, *B. tectorum* effects, chronic grazing disturbance degradation effects, lack of resiliency of Wyoming big sagebrush habitats, the magnitude of damage that has already been done to these (no A-ranked sites even remain) and the synergistic effects of all of these (and other) threats, including drought and stochastic processes.

Our Response: To determine the rate at which wildfire is impacting *Lepidium papilliferum* habitats and how far into the future we can reasonably predict the likely effects of wildfire on the species, we assessed the available data regarding the extent of *L. papilliferum* habitat that is likely to burn each year. We used accurate, site-specific historical fire data to generate an average impact of a highly stochastic process. To do so, in the proposed reconsideration of the final rule, we used two time periods, one more conservative (the last 56 years (to generate the 150 ac/yr (61 ha/yr) rate)) and one estimate assuming potentially accelerated losses to fire, as based on observations over the last 5 years (as an indicator of recent changes, generating the 170 ac/yr (69 ha/yr) rate).

We agree with the commenters that our 5-year estimate is too short a timeframe to accurately reflect the average impact of wildfire, and we have removed this estimate from this final rule. However, we believe our long-term estimate (updated in this final rule to reflect the last 59 years of data, which resulted in a change from 150 ac/yr (61 ha/yr) to a rate of 141 ac/yr (57 ha/yr)) is a reliable estimate using the best available scientific data. We also believe it is a conservative estimate, as it does not account for potentially greater rates of loss due to the likely effects of climate change and increasing coverage of *Bromus tectorum.* We do not narrowly predict that every year 141 ac (57 ha) will burn. We estimate that over the foreseeable future, *on average* the impact of wildfire on unburned habitat will be 141 ac (57 ha) per year.

We recognize that caution should be used in interpreting geospatial information as it represents relatively coarse vegetation information, which may not reflect that some EOs may be located within remnant unburned islands of sagebrush habitat within fire perimeters. However, it is the best available information and provides additional cumulative evidence that increased wildfire frequency is ongoing and, as detailed in the October 8, 2009, final listing rule (74 FR 52014), is likely facilitating the continued spread of invasive plant species and Owyhee harvester ant colony expansion, all of which continue to negatively affect *L. papilliferum* and its habitat.

(9) Comment: Both the State and ISDA commented that livestock use should be removed from the list of threats to *Lepidium papilliferum.* The Idaho State Office of Species Conservation argued that, based on the Service's own analysis, mechanical damage to the plant and its habitat "does not pose a significant risk to the viability of the species as a whole." They added that the threat from livestock is essentially nullified when considering the associated benefits livestock use can have on *L. papilliferum* and its habitat. ISDA added that *L. papilliferum* listing would have more impact on ranchers on public lands than any other group, and that wildfire and the spread of invasive nonnative plant species, like *Bromus tectorum,* have done more to move *L. papilliferum* toward listing than any other factor. Several additional commenters made reference to livestock grazing as it relates to the 2009 final listing rule (74 FR 52014, October 8, 2009). Some of the commenters felt that it should be removed as a threat to *L. papilliferum.* Other commenters felt it should be elevated from a secondary to a primary threat. No new information was provided by these commenters.

Our Response: For the purposes of this rulemaking, we addressed only comments directly relevant to the proposed reconsideration of the final rule, and, therefore, comments revisiting the listing decision that was published on October 8, 2009 (74 FR 52014), if they did not provide any new information that was not already considered, are not addressed in this rule. We fully considered and evaluated livestock use as a potential threat in the 2009 final listing rule (74 FR 52014, October 8, 2009). Because we concluded at that time that livestock use, as currently managed, is not a primary threat to the species, livestock use was not identified as a primary threat to the species in our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), and we did not include it in our foreseeable future discussion. A detailed discussion and analysis of each of the threat factors for *Lepidium papilliferum* can be found in the final listing decision for *L. papilliferum* (published in the **Federal Register** on October 8, 2009 (74 FR 52014).

(10) Comment: The ISDA stated that the Service did not adequately consider biological and innovative controls for invasive nonnative plants as they relate to the foreseeable future of *Lepidium papilliferum.* The ISDA suggested that the Service take these ongoing research projects into consideration since invasive nonnative plant species, such as *Bromus tectorum,* is one of the primary threats to *L. papilliferum,* and these controls could likely be significantly reduced as a threat to the species in the very near future.

Our Response: The Service is encouraged by the emerging invasive nonnative plant controls. However, these invasive nonnative control methods are still being developed and are not yet available on a landscape scale, nor is effectiveness data currently available for these controls, thus accounting for them in our foreseeable future estimation would be no more than speculative. In addition, these biological controls are currently only approved on an experimental basis, not for widespread use, on Federal lands, where 87 percent of the total occupied *Lepidium papilliferum* habitat is located. However, we are hopeful that such methods may prove to be effective in the control of the significant threat posed by invasive nonnative plants on a landscape scale.

Comments From Tribes

(11) Comment: The Shoshone-Bannock Tribes commented that the listing process must clearly recognize the Tribes' off-reservation right to hunt, fish, and gather on unoccupied lands of the United States, and requested that the listing state that the management shall in no way impinge upon Treaty Rights as the Indians understood them. They expressed that treaties of the Federal Government are the supreme law of the land, and their Treaty Rights should be clearly stated upfront and foremost in the listing process. They added that, under Article 5 of the 1868 Treaty with the Eastern Band Shoshoni and Bannock (15 Stat. 673), the Federal Government agreed that all cases of depredation on person or property will be taken to the Commissioner of Indian Affairs, now called the Assistant Secretary of the Interior for Indian Affairs, for due consideration. The Tribes reiterated that the Service has a trust responsibility to duly consider the vested rights and interests of the Tribes.

Our Response: In response to the concerns expressed by the Shoshone-Bannock Tribes and in accordance with Secretarial Order 3206, we recognize our trust responsibility and treaty obligations toward Indian tribes and tribal members. We also acknowledge that tribal trust resources, either on or off Indian lands, are protected by a fiduciary obligation on the part of the United States. *Lepidium papilliferum* is not known to occur on tribal lands, and we are not aware of specific tribal activities that may conflict with conservation of slickspot peppergrass. However, if new information reveals a need to address conflict between Tribal activities and the conservation needs of the species, we will work with the Tribes, in accordance with our Federal-Tribal trust responsibilities and obligations, to promote conservation of the species and its habitat.

Public Comments

(12) Comment: One commenter argued that the Service did not analyze the considerable new scientific information that highlights the grave threats grazing disturbance poses to sagebrush ecosystems. Specifically, the commenter stated that, in the Factors Affecting the Species section of the proposed reconsideration of the final rule (79 FR 8416; February 12, 2014), the Service cites much too short historical fire-return intervals for its estimation of fire frequency and return intervals. The commenter suggested replacing the interval we referenced (60–100 years) with the fire-return intervals used in the greater sage-grouse 12-month finding, which included intervals up to 350 years (75 FR 13910, p. 14016; March 23, 2010).

Our Response: This commenter provided numerous documents for our consideration. Many of the documents were previously submitted or had already been cited and considered in the 2009 final listing rule (74 FR 52014, October 8, 2009). However, some of the information provided was new information that has become available since our 2009 final listing rule. Although this new information did not specifically address direct or indirect impacts to *Lepidium papilliferum* and slickspots from livestock use, the commenter provided many general references that describe livestock impacts to sagebrush steppe habitats. After careful consideration of the new information provided by the commenter, we conclude that, while it supports and builds on information that we used in the 2009 final listing rule, it does not alter our 2009 listing determination. As we describe in the 2009 final listing rule, there are potential negative impacts to *L. papilliferum* populations and slickspots resulting from livestock grazing, but livestock use in areas that contain *L. papilliferum* has the potential to result in both positive and negative effects on the species, depending on factors such as stocking rate and season of use. The new information submitted does not alter our earlier conclusion that livestock use, as currently managed, is not a primary threat to the species.

The commenter provided literature that discusses the role that livestock grazing plays in contributing to annual grass cover. As discussed in the 2009 final listing rule (74 FR 52014, October 8, 2009), we acknowledge there are some case studies from western North America that suggest that grazing plays an important role in the decrease of native perennial grasses and an increase in dominance by nonnative annual species (as described in Reisner *et al.* 2013, which was provided by the commenter). However, invasion by nonnative grasses has been found to occur both with and without grazing in some areas. Today, nonnative annual plants such as *Bromus tectorum* are so widespread that they have been documented spreading into areas not impacted by disturbance (Piemeisel 1951, p. 71; Tisdale *et al.* 1965, pp. 349–351; Stohlgren *et al.* 1999, p. 45); therefore, the absence of livestock use no longer protects the landscape from invasive nonnative weeds (Frost and Launchbaugh 2003, p. 44), at least with respect to *B. tectorum.*

The commenter also provided literature that discusses the value of passive restoration in the form of reducing cumulative cattle grazing, as a means of restoring habitats, as well as research that raises concerns regarding proposals to use cattle grazing to control *Bromus tectorum* in ecosystems where remnant bunchgrass communities persist. In the 2009 final listing rule (74 FR 52014, October 8, 2009), we described that with careful management, livestock grazing may potentially be used as a tool to control *B. tectorum* (Frost and Launchbaugh 2003, p. 43) or, at a minimum, retard the rate of invasion (Loeser *et al.* 2007, p. 95), but that others have suggested that, given the variability in the timing of *B. tectorum* germination and development, and its ability to spread vegetatively, effective control of *B. tectorum* through livestock grazing may be a challenge (Hempy-Mayer and Pyke, 2008, p. 121).

In the 2009 final listing rule (74 FR 52014, October 8, 2009), we also specifically recognized the potential for negative impacts to *Lepidium papilliferum* populations and slickspots that may result from seasonal, localized trampling events. However, with the implementation of conservation measures to minimize potential direct and indirect impacts of livestock to *L. papilliferum,* such as restricting livestock access to areas occupied by *L. papilliferum* when slickspot soils are wet, and thus most vulnerable to damage, we consider livestock use to be a lesser threat to the species than the primary threats posed by the altered wildfire regime and associated increase in nonnative, invasive plant species within the range of *L. papilliferum.*

Evidence of the direct and indirect potential impacts to *L. papilliferum* and slickspots from livestock use is still relatively limited. We acknowledged in the 2009 final listing rule (74 FR 52014, October 8, 2009) that the available data may not be adequate to detect time-dependent issues associated with livestock use, as only 5 years of HIP data were available when the analysis was conducted (Sullivan and Nations 2009, p. 137). However, since the commenter did not provide any new data specific to *L. papilliferum,* the HIP analysis presented in the 2009 final listing rule still represents the best species-specific data available (as described in detail in "Livestock Use" under Factor A in the *Summary of Factors Affecting the Species* section of the 2009 final listing rule).

Taking all of the new information into account, we still conclude that livestock will have a negative impact on *Lepidium papilliferum,* primarily through mechanical damage to individual plants and slickspot habitats; however, the current livestock management conditions and associated conservation measures address this potential threat such that it does not pose a significant risk to the viability of the species as a whole. However, we continue to encourage the ongoing implementation of conservation measures and associated monitoring to ensure potential impacts of livestock trampling to the species are avoided or significantly minimized. Because we limited our discussion of foreseeable future to the threats we consider significant in terms of contributing to the present or threatened destruction, modification, or curtailment of *L. papilliferum's* habitat or range, as identified in the 2009 final listing rule (74 FR 52014, October 8, 2009), and because we concluded that the new information provided by the commenter does not alter our previous conclusion that livestock use is a secondary threat to *L. papilliferum,* we did not include an updated summary of livestock use in this final rule. We have included the new references provided by the commenter in our decision record, which can be accessed by contacting the Idaho Fish and Wildlife Office (see **ADDRESSES**, above). In reference to the commenter's request that we use more recently described fire-return intervals, we have updated this reference in the Factors Affecting the Species section of this final rule. However, it should be noted that, in our calculation of foreseeable future, we relied on empirical site-specific historical fire data, not general sagebrush-steppe fire-return interval estimates.

(13) Comment: One commenter expressed that *Bromus tectorum* risk mapping should be considered in this rule to determine foreseeable future.

Our Response: We carefully reviewed the information provided by the commenter. The commenter referenced a publication (Peterson 2007), which provides a map of annual grasses in the Owyhee Uplands developed in spring 2006. This is a dated, although still highly regarded, study. However, because it does not adequately cover *Lepidium papilliferum* habitat, we cannot use this information in a rangewide analysis for the species. In addition, this is a single-year mapping effort, making comparisons over time (as we did for our wildfire analysis) impossible. In this rule, we noted a geospatial analysis conducted by Stoner (2009, p. 81), which indicates that by 2008 approximately 20 percent of the total area of all *L. papilliferum* EOs rangewide was dominated by introduced invasive annual and perennial plant species. However, because this analysis only considered areas that were 'dominated' by introduced invasive species, it does not provide a comprehensive estimate of invasive species presence within the range of *L. papilliferum,* and also cannot be used to determine the rate at which invasive nonnative plant species are impacting *L. papilliferum* habitats and how far into the future we can reasonably predict the likely effects of invasive nonnative species on *L. papilliferum.* Because we are unaware of any other site-specific *Bromus tectorum* or invasive nonnative plant species data that has been repeated over time, and because of the synergistic interaction between wildfire and the invasion of nonnative plant species, by association, we assume that future colonization of *L. papilliferum* habitat by invasive nonnatives will proceed on approximately the same timetable as wildfire.

(14) Comment: One commenter felt that current management practices are inadequate to protect or aid in the recovery of *Lepidium papilliferum.* The commenter cited as an example that the Candidate Conservation Agreement (CCA) for *L. papilliferum* states that water troughs near EOs will be moved or turned off, and, according to the commenter, this has not occurred. The commenter added that according to HIP monitoring several sites have been negatively disturbed by hoof action. Another commenter stated that the HIP monitoring for *L. papilliferum* shows declines in populations across its entire range and this decline is in spite of abundant spring moisture in 2013. The commenter argued that this decline shows a lack of adequate regulatory mechanisms to protect and conserve the species.

Our Response: We agree that, to date, we have not been notified of any livestock troughs that have been removed or turned off for *Lepidium papilliferum* conservation. However, HIP monitoring has detected a decline in livestock trampling triggers tripped over the 10 years of monitoring (the trampling "trigger" refers to a threshold for trampling set in the CCA, which was developed by the State of Idaho, BLM, and others in 2003, and is defined as breaking through the restrictive layer under the silt surface area of a slickspot during saturated conditions; State of Idaho *et al.* 2006, p. 9). The highest number was eight triggers tripped in 2007; more recent years have shown a low incidence of livestock triggers tripped (one livestock trigger tripped in 2012, zero livestock triggers tripped in 2013, and two livestock triggers tripped in 2014). While it is true that 2013 HIP monitoring resulted in the lowest *L. papilliferum* plant numbers observed in the 10 years of the HIP monitoring data available to date (6,351 plants), the spring of 2013 was dry and warm. Total precipitation from March through June 2013 in Boise, Idaho, was 2.49 inches (in) (6.32 centimeters (cm)). In contrast, March through June 2014 total precipitation was 5.36 in (13.6 cm) (National Weather Service, 2015). The 2014 HIP monitoring resulted in 45,569 total plants observed on HIP transects, the third highest number of plants observed over the 10 years of HIP monitoring (Kinter 2015, *in litt.*). It appears that the lower plant numbers in 2013 were likely related to climate conditions, although we do recognize that habitat conditions for *L. papilliferum* continue to decline across the range of the species.

(15) Comment: One commenter requested that additional factors be considered in the foreseeable future determination, such as seedings of invasive *Bassia prostrata* and *Agropyron cristatum* (crested wheatgrass) on BLM, State, or private lands. This same commenter also stated that our estimates of foreseeable future do not adequately address synergistic effects of multiple threats and disturbances and they do not address the non-linear rate of change in *Lepidium papilliferum* habitats and the ecological process distortion already set in motion. For example, the commenter suggested that slickspots with moderate levels of weeds are exceedingly likely to have surfaces choked with weeds as chronic livestock degradation continues. The commenter added that habitat degradation, once a considerable amount of weeds are present, is not reversible in slickspots.

Our Response: For the purpose of this rulemaking, we limited our discussion of foreseeable future to the threats we consider significant in terms of contributing to the present or threatened destruction, modification, or curtailment of *Lepidium papilliferum's* habitat or range. These include the two primary threat factors: Altered wildfire regime (increasing frequency, size, and duration of wildfires), and invasive, nonnative plant species (*e.g., Bromus tectorum*), as well as the contributing threat factors of planned or proposed development, habitat fragmentation and isolation, and the emerging threat from seed predation by Owyhee harvester ants. As acknowledged in our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), we recognize that our model is relatively simple, assuming, for example, that the impacts to habitat from wildfire will continue to occur at a constant rate over time, when in reality the extent of area affected by wildfire will vary from year to year. Although a far more complex and exhaustive modeling effort might be possible that would incorporate elements of variability and stochasticity, the Act requires that we make our determinations based on the best scientific and commercial data *available* (emphasis ours). For our purposes of developing a reliable estimate of a timeframe within which *L. papilliferum* is likely to become endangered, we believe this projection makes reasonable use of the best scientific data available to predict the effects of wildfire on the species over time. As noted in the final rule (74 FR 52014, October 8, 2009), because of the close and synergistic association between the occurrence of wildfire and invasion by nonnative plants, followed by habitat loss and fragmentation, we believe this timeframe similarly applies to the primary threat of invasive nonnative plants and fragmentation and isolation as well.

(16) Comment: One commenter suggested that a direct relationship between climate change, wildlands fire, and *Lepidium papilliferum* population dynamics is mostly conjecture and not supported by science. The commenter stated that the climate change portion of this equation is based on the General Circulation Model and the Parallel Climate Model, which, like the Global Climate Models, apply to large areas, and do not necessarily apply to local situations like the Owyhee Desert or along the Snake River. The commenter added that the projected future effects of climate change at this time are hypothetical, and the effects of the stable climate over the past decade further complicate climate change models, obscuring hypothetical primary threats from wildfire and *Bromus tectorum*. Another commenter commented that the Service did not consider new climate change information. The commenter argued that impacts from wildfire will not occur over a constant rate, particularly when climate change effects are considered, causing our model to likely greatly overestimate the time period until *Lepidium papilliferum* is endangered.

Our Response: The Service recognizes that climate change is an important issue with potential effects to listed species and their habitats. We also recognize there are scientific differences of opinion on many aspects of climate change. In the 2009 final listing rule (74 FR 52014, October 8, 2009), we relied primarily on the IPCC 2007 synthesis document, which presents the consensus view of a large number of experts on climate change, and which projected that the changes to the global climate system in the 21st century will likely be greater than those observed in the 20th century (IPCC 2007, p. 45). According to the more recent IPCC 2013 synthesis document (p. 7), which we have incorporated into this final listing rule, current trends in the climate system—increasing temperature, increasing duration and intensity of drought, decreasing snowpack, increasing heavy precipitation events, and other extreme weather—are likely to continue through the 21st century.

Although current climate change effects are documented in the western United States, the direct, long-term impact from climate change to *Lepidium papilliferum* is yet to be determined, and new studies have not significantly altered our understanding of how climate change is likely to affect *L. papilliferum* and its habitat. However, while the response of *L. papilliferum* to habitat changes resulting from climate change remain difficult to predict, even under conservative projections of the consequences of future climate change, we anticipate that in the foreseeable future climatic conditions will favor further invasion by *Bromus tectorum,* that fire frequency will continue to increase, and that the extent and severity of fires may increase as well. The positive correlations between these factors are well supported in the peer-reviewed literature, as referenced in the final listing rule and this final rule.

As stated elsewhere in this rule, for the purpose of this document, we limited our discussion of foreseeable future to the threats we consider significant in terms of contributing to the present or threatened destruction, modification, or curtailment of *L. papilliferum's* habitat or range. We acknowledge that our foreseeable future estimate does not account for potentially greater rates of loss due to the likely effects of climate change and increasing coverage of *Bromus tectorum.* Our estimate is, therefore, a conservative estimate. However, we note that, even if revised calculations resulted in a potentially shorter period of time before *L. papilliferum* reaches the conditions under which we consider it to be endangered, our ultimate determination, that it currently meets the definition of a threatened species according to the Act, would remain the same. Our listing determination would change only if new information regarding existing threats or potential additional threats indicated that *L. papilliferum* is currently in danger of extinction, and we have no scientific data at this point in time to suggest that this is the case. A complete description of the potential effects from climate change and our evaluation of this threat is found in Factor E of the *Summary of Factors Affecting the Species* discussion in the 2009 final listing rule.

(17) Comment: One commenter expressed that it is unreasonable to assume, without actual population estimates and without understanding threats, that *Lepidium papilliferum* is in danger of extinction within the next 36 to 47 years, or the foreseeable future. The commenter questioned our description of the future endangered status for *L. papilliferum* because actual rangewide population numbers are unknown. The commenter went on to add that hypothesizing the number of years (approximately 36 to 47 years) when 80 to 90 percent of its remaining habitat will have been affected, based on the ongoing rates of *L. papilliferum* habitat impacted by wildfire, is meaningless, because 100 percent of the range burns at regular intervals and actual populations of *L. papilliferum* are unknown.

Our Response: The Act requires that we make listing decisions based on the best scientific and commercial data available. As discussed elsewhere in this document (see our response to Comment 6, above), past population trend data were not used in making the listing decision for *Lepidium papilliferum,* nor did we attempt to project population trends into the future, as "it would be inappropriate to rely on this model to predict any future population trajectory for *L. papilliferum*" (see pp. 52022–52025 of the October 8, 2009, listing rule, 74 FR 52014). Systematic rangewide surveys for *L. papilliferum* have not occurred. However, occupied slickspot sites and EOs discovered since the 2009 listing have not added substantially to our knowledge of where the species exists; these new sites all occur within the known range of the species. Furthermore, we must make our determination on the basis of the information available at this time, and the Act does not allow for delay of our decision until more information about the species and its habitat are available. While some uncertainty will always exist, the existing information used in this final rule represents the best available scientific information upon which to make a foreseeable future determination for this species. We continue to encourage future survey and monitoring work for this species and its habitat.

With regard to our estimate of when *Lepidium papilliferum* would become an endangered species (in danger of extinction), we disagree with the commenter's characterization of our evaluation as a "hypothesis." Our estimated timeframe for determining when *L. papilliferum* will reach the point when 80 to 90 percent of its remaining unburned habitat will have been affected by fire is based on empirical data collected over a period of 59 years, which allowed us to project forward based on the average annual rate at which previously unburned *L. papilliferum* habitat has been affected by wildfire. We consider this to represent the best scientific data available with regard to the likely rate at which the primary threat of wildfire, and, by association, the rate at which invasive nonnative plants, will affect the status of the species over time.

(18) Comment: One commenter questioned what we meant by "complete count" of plants, and asked why we are attempting to list a species when much land remains to be surveyed for *Lepidium papilliferum.* The commenter cited the following statement in the proposed reconsideration of the final rule (79 FR 8416, February 12, 2014): "The discovery of some new occupied sites is not unexpected given not all potential *L. papilliferum* habitats in southwest Idaho have been surveyed." The commenter added that there has never been a survey of proper sample size to draw any conclusions regarding the dynamics of the *L. papilliferum* population and suggested that, from what little has been surveyed, the average number of plants per transect has increased over the last several years compared to the early survey years.

Our Response: As described in the 2009 final listing rule (74 FR 52014, October 8, 2009), "complete count" refers to making a complete count of all aboveground plants (each individual) observed on HIP transects during annual monitoring from 2005 to the present (as opposed to recording plant abundance as a range of values, which was done during HII transect monitoring from 1998–2002). Comparison of the average number of plants observed during HIP transect monitoring (2005–present) with plant numbers collected during HII monitoring (1998–2002) is problematic, as the two monitoring strategies used differing methodologies. For example, for HII monitoring, the same slickspots were not monitored each year within transects, and a range of plant numbers, rather than recording complete counts as was done for the HIP monitoring, was reported. In response to the comment that much of the land remains to be surveyed for *Lepidium papilliferum,* please see our response to Comment 17.

(19) Comment: One commenter questioned the biological reason for the 80–90 percent threshold of habitat loss at which the species will be in danger of extinction. They asked if the Service will automatically declare *Lepidium papilliferum* in danger of extinction when the 80–90 percent loss of unburned habitat is reached without regard to the actual population size.

Our Response: Any change in status under the Act always requires a public rulemaking and is never automatic. In accordance with section 4(a)(1)(b) of the Act, the Secretary determines whether any species is an endangered species or threatened species because of any of the five factors, which are described above under *The Basis for Our Action.* The Secretary makes this determination based on the best scientific and commercial data available at the time of the status review. In response to the commenter's question regarding the biological reason for the 80–90 percent threshold of habitat loss, we based this estimate on our conclusion that at that point *Lepidium papilliferum* would most likely become in danger of extinction, because in our best professional judgment under these conditions the species would most likely persist only in a small number of isolated EOs, most likely with small populations that would be fragmented from other extant populations, such that the remaining populations would be incapable of interchange sufficient to maintain the long-term existence of the species. We acknowledge that this is a qualitative assessment of the threshold, based on fundamental principles of conservation biology, and that it relies upon our best estimate of when these conditions would be met in the future using the best available scientific data regarding the action of the primary threats on the species and its habitat. There is no precise mathematical formula available specific to *L. papilliferum* (nor is there for any species) that provides for a definitive quantitative assessment capable of pinpointing the exact moment in time when the status of the species would transition to "in danger of extinction." We did not receive an alternative suggestion of what might be more reasonable, nor did we receive any evidence that our approach is incorrect.

(20) Comment: One commenter stated that the Service's statement that "[b]ecause we still do not see strong evidence of a steep negative population trend for the species . . . we believe that *Lepidium papilliferum* is not in immediate danger of extinction" raises the question of how "immediate" the danger of extinction must be in order to qualify a species for listing as "endangered" rather than "threatened." The commenter suggested that the Service's description of threats to the species indicates that *L. papilliferum* is not merely "likely to become an endangered species within the foreseeable future," but is in fact "in danger of extinction." Another commenter agreed, stating the Service's foreseeable future estimate of 50 years is overly optimistic. The commenter argued that *L. papilliferum* is crossing the threshold to becoming an endangered species right now. The commenter added that the Service may arrive at this conclusion if we used the current wildfire return intervals for Wyoming big sagebrush communities, and fully and fairly incorporated the broad spectrum of livestock degradation effects to the sagebrush matrix and slickspots.

Our Response: In considering potential threatened species status for *Lepidium papilliferum,* we described what endangered species status (in danger of extinction throughout all or a significant portion of its range) for *L. papilliferum* would be. As described in our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), we believe *L. papilliferum* will be in danger of extinction (an endangered species) when the anticipated and continued synergistic effects of increased wildfire, invasive nonnative plants, development, and other known threats affect the remaining extant *L. papilliferum* habitats at a level where the species would persist in only a small number of isolated EOs, most likely with small populations that would be fragmented from other extant populations. In order to estimate when this might occur, we chose a threshold of 80 to 90 percent loss of or damage to the currently remaining unburned habitat. At present, we estimate there are approximately 7,477 ac (3,025 ha) of *L. papilliferum* habitat remaining that have not yet been negatively impacted by fire. Based on the observed rates of habitat impact due to wildfire, we can reliably predict that approximately 80 to 90 percent of the remaining *L. papilliferum* habitat not yet impacted by wildfire will be negatively affected by wildfire within an estimated 43 to 48 years. Therefore, while we conclude the species is not at immediate risk of extinction, our analysis has led us to conclude that *L. papilliferum* is likely to become an endangered species within the foreseeable future, based on our assessment of that period of time over which we can reasonably rely on predictions regarding the threats to the species. Based on our analysis of the best scientific and commercial data available, we have no information to suggest that the status of *L. papilliferum* is such that it is currently in danger of extinction, and we conclude that threatened status is appropriate for this species.

For the purpose of this document, we limited our discussion of foreseeable future to the threats we consider significant in terms of contributing to the present or threatened destruction, modification, or curtailment of *Lepidium papilliferum's* habitat or range. These include the two primary threat factors: Altered wildfire regime (increasing frequency, size, and duration of wildfires), and invasive, nonnative plant species (*e.g., Bromus tectorum*); as well as contributing threat factors of planned or proposed development, habitat fragmentation and isolation, and the emerging threat from seed predation by Owyhee harvester ants. We fully considered and evaluated livestock use as a potential threat in the 2009 final listing rule (74 FR 52014, October 8, 2009); because we did not conclude that this activity poses a primary threat to the species, we did not include it in our foreseeable future discussion. As described in the section Factors Affecting the Species of this document, we additionally considered any new information that has become available regarding stressors to the species since our 2009 final listing rule. As this new information was largely congruent with our original determination, it did not lead us to alter our conclusions with regard to those stressors that pose a significant threat to the species at this time.

(21) Comment: One commenter stated that once the species is diminished to the point that the Service deems it ''in danger of extinction,'' the remaining 10 to 20 percent of its present habitat would be so highly fragmented that it would detrimentally affect successful insect pollination and genetic exchange, leading to a reduction in genetic fitness and genetic diversity, and a reduced ability to adapt to a changing environment. The commenter added that there would be little probability of recolonization of formerly occupied sites at this point, and remaining small, isolated populations would be highly vulnerable to local extirpation from a variety of threats. The commenter was concerned that it will not be possible to recover the species at that point.

Our Response: We acknowledge the commenter's concern, and note that this very concept underlies the rationale for the ''threatened species'' classification under the ESA—it provides for the conservation of species before they are in danger of extinction, when recovery is more difficult. The goal of the ESA is the recovery of listed species to levels where protection under the ESA is no longer necessary. As the commenter indicated, it is, in some cases, more challenging to recover a species that meets the definition of endangered than one that meets the definition of threatened. Section 3 of the Act defines an endangered species as ''any species which is in danger of extinction throughout all or a significant portion of its range'' and a threatened species as ''any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range.'' In other words, the primary statutory difference between a threatened species and an endangered species is the timing of when a species may be in danger of extinction, either presently (endangered) or in the foreseeable future (threatened). Our analysis indicates that, although *Lepidium papilliferum* is likely to become in danger of extinction in the foreseeable future, it is not currently on the brink of extinction and does not meet the definition of endangered. By listing this species as threatened, we seek to prevent it from becoming endangered. Furthermore, we will continue to review new information and monitor the status of this species in order to evaluate whether changes to the species' classification are appropriate in the future.

(22) Comment: One commenter inquired how EO ranks have changed since 2006. The commenter stated that we did not provide current mapping of sagebrush habitats or the criteria and vegetation mapping methodology, based on current vegetation data, that we used to establish a baseline. The commenter felt this was important, because the Service requested comment on our choice of the 80 to 90 percent threshold. The commenter requested the baseline status of all EOs in 2014.

Our Response: We did not provide mapping of sagebrush habitats because our geospatial data analysis was specific to *Lepidium papilliferum* EO area affected by wildfire over 50 years (from 1957 to 2007), not sagebrush habitats in general. ''Habitat'' in the referenced sentence refers specifically to *L. papilliferum* habitat. In addition, in our determination of the 80 to 90 percent threshold, we utilized recent fire-history data, not Idaho Natural Heritage Program (INHP) EO rankings. Our best scientific data available at this time are the 2005 INHP EO ranks. INHP is currently in the process of re-evaluating the EO ranks; however, the updated ranks are not yet available. Please refer to the Factors Affecting the Species section of our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) for more details on our rationale supporting our conclusion of the 80–90 percent threshold; see also our response to Comment 20, above.

(23) Comment: One commenter requested clarification on how we estimated the approximately 7,567 ac (3,064 ha) of *Lepidium papilliferum* habitat not yet negatively impacted by wildfire, and asked if this estimate includes 2013 wildfires. The commenter also inquired what vegetation mapping and site-specific information was used, when and how it was collected, and what the boundary was of the total habitat area being considered. The commenter also requested the mapping information.

Our Response: We have updated our evaluation to reflect new fire data that has become available since the publication of the proposed reconsideration of the final rule, including data from 2013 to 2015. This new information indicates that over a period of 59 years (1957 to 2015), the perimeters of 149 wildfires occurring within the known range of *Lepidium papilliferum* have burned approximately 8,348 ac (3,378 ha) (Hardy 2016, *in litt.*). We determined, using GIS, that there are approximately 7,477 ac (3,025 ha) of *L. papilliferum* habitat remaining that have not yet been negatively impacted by wildfire, by subtracting the total area of *L. papilliferum* habitat that has burned (8,348 ac (3,378 ha)) from the total *L. papilliferum* EO area of 15,825 ac (6,404 ha), which was calculated using the new fire information that has become available since 2009, and considering only impacts to new, previously unburned areas over the past 59 years (1957–2015). For a more detailed explanation of how this was calculated, please refer to the *Summary of Factors Affecting the Species,* Altered Wildfire Regime section of this document (above).

In reference to the commenter's questions regarding the data and mapping used in our analysis, we used *L. papilliferum* EOs from the January 2015 IFWIS data export and wildfire data from the BLM up to and including 2015. This information is located in our decision record, which can be accessed by contacting the Idaho Fish and Wildlife Office (see **ADDRESSES**, above).

(24) Comment: One commenter stated that we did not estimate the acres of

occupied *Lepidium papilliferum* habitat that was burned before any surveys had been conducted and EOs applied, with much of *L. papilliferum* long ago wiped out by the combination of the fire effects, BLM seeding of crested wheatgrass, *Bassia prostrata* or other exotic species, and continued grazing disturbance with minimal post-fire rest. The commenter inquired about how much of the land area of potential habitat has burned, or has burned and then been aggressively seeded and grazed. Furthermore, the commenter wanted to know how much of the potential habitat experienced an increase in invasive nonnative species as a consequence.

Our Response: We acknowledge that having more historical information on the distribution and abundance of *Lepidium papilliferum* before surveys were conducted and EOs identified would be helpful; however, that information does not exist. We have based our determinations on the best available scientific information; therefore, we used current EO data only.

(25) Comment: One commenter stated that to base the foreseeable future model solely on the burned acreage and not on the actual or reliably estimated population parameters is unsupportable. The commenter explained that the only way for a foreseeable future model to be valid for a declining species is to first show that the population is actually declining, and then have a significant rate of decline over a scientifically determined large enough population sample size to be able to draw valid conclusions.

Our Response: Projecting when a population reaches a certain level requires accurate population numbers. As stated in our 2009 final listing rule (74 FR 52014, October 8, 2009), past population trend data were not used in making the listing decision for *Lepidium papilliferum* as ''it would be inappropriate to rely on this model to predict any future population trajectory for *L. papilliferum*'' (see pp. 52022–52025 of the 2009 final listing rule). In that rule we described that there are many uncertainties associated with both the data and the model used that preclude our ability to make such a projection, including the great annual variability in aboveground numbers of *L. papilliferum* and the confounding influence of the long-lived seedbank. Therefore, our analysis of the foreseeable future for the purposes of assessing the status of *L. papilliferum* relies on the foreseeability of the relevant threats to the species over time. The primary threats of wildfire and nonnative invasive plants, especially *Bromus tectorum,* are currently affecting the species throughout its limited range, and we find that using accurate, site-specific historical fire data is a more reliable measure for predicting the conservation status of this species into the foreseeable future.

In response to the comment regarding population declines, as stated in our 2009 final listing rule (74 FR 52014, October 8, 2009), we have information indicating a statistically significant negative association between *L. papilliferum* abundance and wildfire, and between *L. papilliferum* abundance and cover of *B. tectorum* in the surrounding plant community. It is this significant correlation between these threat factors and the population response of the species that obviates the need for statistically significant population trend data and enables us to rely on the reasonably foreseeable effects of these threat factors acting on *L. papilliferum* to predict that it is likely to become in danger of extinction within the foreseeable future.

(26) Comment: One commenter expressed that it is not firmly established scientifically that the threats of wildfire and invasive nonnative plants are currently affecting *Lepidium papilliferum* throughout its range. The commenter stated that it is unknown whether the ''hypothetical'' threats described in both the 2009 final listing rule (74 FR 52014, October 8, 2009) and our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014), including development, habitat fragmentation, and climate change, will increase into the foreseeable future. The commenter added that populations will continue to cycle. Low numbers have been attributed to unusually cold and wet springs, while high population counts occur during extremely favorable climactic elements that resupply the *L. papilliferum* seed bank and populations. The populations will also cycle due to weather variables that are not currently apparent. The commenter reiterated that there is not strong evidence of a steep negative population trend for this species, and noted that although the total number of *L. papilliferum* plants counted in HIP monitoring in 2011 and 2012 were the lowest since 2005, these numbers can, according to Kinter (2012 *in litt.*), fluctuate widely from one year to the next and are probably not great cause for concern.

Our Response: As discussed in our response to Comment 25, above, we agree that the extreme variability in plant numbers from year to year precludes our ability to rely strictly on population trend data to inform us as to the likely future status of the species. Section 4 of the Act and its implementing regulations (50 CFR part 424) set forth the procedures for adding species to the Federal Lists of Endangered and Threatened Wildlife and Plants. A species may be determined to be an endangered or threatened species due to one or more of the five factors described in section 4(a)(1) of the Act: (A) The present or threatened destruction, modification, or curtailment of its habitat or range; (B) overutilization for commercial, recreational, scientific, or educational purposes; (C) disease or predation; (D) the inadequacy of existing regulatory mechanisms; or (E) other natural or manmade factors affecting its continued existence. Listing actions may be warranted based on any of the above threat factors, singly or in combination.

Relatively limited new data regarding population abundance or trends have become available since our 2009 final listing rule (74 FR 52014, October 8, 2009). As discussed in the section Factors Affecting the Species of this final rule, the new information generally supports our 2009 conclusions on the present distribution of *Lepidium papilliferum,* its status and population trends, and how the various threat factors are affecting the species. We acknowledge that, similar to our findings in our 2009 final listing rule, we do not see strong evidence of a steep negative population trend for the species. However, as stated in our 2009 final listing rule, we have information indicating a statistically significant negative association between *L. papilliferum* abundance and wildfire, and between *L. papilliferum* abundance and cover of *Bromus tectorum* in the surrounding plant community. Our analysis of the foreseeable future for the purposes of assessing the status of *L. papilliferum* relies on the foreseeability of the relevant threats to the species over time. We anticipate the continuation or increase of all of the significant threats to *L. papilliferum* into the foreseeable future, even after accounting for ongoing and planned conservation efforts, and we find that the best available scientific data indicate that the negative consequences of these threats on the species will likewise continue at their current rate or increase. These data indicate that population declines and habitat degradation will likely continue in the foreseeable future to the point at which *L. papilliferum* will become in danger of extinction.

We have analyzed and assessed known threats impacting *L. papilliferum,* and used the best available information to carefully consider what effects these known threats will have on this species in the future, and over what timeframe, in order to determine what constitutes the foreseeable future for each of these known threats. Based on an assessment of the best scientific and commercial data available regarding the present and future threats to the species, we conclude that threatened status should be reinstated for *L. papilliferum.* Please refer to the Factors Affecting the Species section of our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) for an analysis of the available data used in our determination. Also refer to our response to Comment 25 for a discussion of our decision to use wildfire data, as opposed to trend data, to analyze the foreseeable future.

In regard to the commenter's statement concerning the 2011 and 2012 population counts, we acknowledge that aboveground numbers of *L. papilliferum* individuals can fluctuate widely from one year to the next. Demonstrating this fact, since the proposed reconsideration of the final rule was published (79 FR 8416, February 12, 2014), we have received 2 additional years of HIP monitoring data (2013 and 2014). The 2013 HIP monitoring resulted in the lowest *L. papilliferum* plant numbers (6,351 plants) observed in the 10 years of the HIP monitoring data available to date; however, the 2014 HIP monitoring resulted in 45,569 total plants observed on HIP transects, the third highest number of plants observed over the 10 years of HIP monitoring (Kinter 2015, *in litt.*). In our proposed reconsideration of the final rule, we had stated that low counts of plants observed in 2011 and 2012 were potentially a cause for concern. We do maintain that habitat conditions for *L. papilliferum* continue to decline across the range of the species; however, we agree with the commenter that such a statement [that low numbers in any particular year may be a cause of concern] is not appropriate, given that numbers of above-ground individuals of *L. papilliferum* can vary so widely from one year to the next; therefore, we have removed this statement from the final rule.

(27) Comment: One commenter suggested that wildfire damage to biological soil crust and nonnative plants invading slickspots have a potential connection that needs further analysis. The commenter explained that volatile oils have been extracted from wild mustards in the genus *Lepidium,* and mustard oil extracts can suppress growth of other plant species due to the release of toxic substances. Garlic mustard (*Alliaria petiolata*), another member of the mustard family (Brassicaceae), to which *Lepidium* species belong, can phytochemically suppress soil fungi and, thus, the release of mustard oil can, therefore, impact the formation and maintenance of the soil crust. The commenter suggested that *Lepidium* species can thus negatively impact the soil crust, as opposed to the reverse scenario—soil crusts (or lack thereof) having a negative impact on *Lepidium* species. In addition, the commenter stated that *Bromus tectorum* is considered a facultative host of arbuscular mycorrhizal fungi (AMF); however, specific information about interactions between *B. tectorum* and AMF remains unknown. For example, an invasive garlic mustard inhibits ectomycorrhizal fungi, and is able to outcompete native plants. Therefore, the commenter asked that the relationship between *Lepidium papilliferum,* mustard oil, and *L. papilliferum* and *B. tectorum* competition be researched before the Service concludes that *B. tectorum* is outcompeting *L. papilliferum.*

Our Response: Evidence that *Bromus tectorum* is likely displacing *Lepidium papilliferum* is provided by Sullivan and Nations' (2009, p. 135) statistical analyses of *L. papilliferum* abundance and nonnative invasive plant species cover within slickspots. Working with 5 years of HIP data collected from 2004 through 2008, Sullivan and Nations found that the presence of other plants in slickspots, particularly invasive exotics, such as *Bassia prostrata,* a seeded nonnative plant species, and *B. tectorum,* was associated with the almost complete exclusion of *L. papilliferum* from those microsites (Sullivan and Nations 2009, pp. 111–112). According to their analysis, the presence of *B. tectorum* in the surrounding plant community shows a consistently significant negative relationship with the abundance of *L. papilliferum* across all physiographic regions (Sullivan and Nations 2009, pp. 131, 137), and a significant negative relationship with *L. papilliferum* abundance within slickspots in the Snake River Plain and Boise Foothills regions (Sullivan and Nations 2009, p. 112). The Act directs the Service to make determinations based on the best *available* data at the time the decision is being made.

(28) Comment: Regarding the statement in our proposed reconsideration of the final rule (79 FR 8416, February 12, 2014): "In other words, we consider a prediction to be reliable if it is reasonable to depend upon it in making decisions, and if that prediction does not extend past the support of scientific data or reason so as to venture into the realm of speculation," a commenter felt this statement conflicts with what the Service proposed to do. The commenter suggested that to extend past the bounds of our scientific data is to venture into the realm of speculation, but the only data the Service has was shown in table 2, and that data is based on too small a sample size to say anything definitive about *Lepidium papilliferum* population growth or decline. The commenter added that, even with the poor survey size, there is nothing that will allow one to extrapolate out 1 year, much less to 50 years.

Our Response: The proposed reconsideration of the final rule (79 FR 8416, February 12, 2014) did not contain a table 2. We also referred to the October 8, 2009, final listing rule (74 FR 52014) to see whether the commenter may have been referring to a table in that document; however, table 2 in the 2009 rule shows a list of extant EO ranks across the range of the species. Therefore, we are unclear to which data the commenter is referring regarding this specific comment. However, in response to the assertion that our decision is speculative, we disagree. We have analyzed and assessed the known threats impacting the species, and used the best available information to assess what effects these threats will have on the species into the future, and over what timeframe, in order to determine what constitutes the foreseeable future as it relates to these threats. We believe our analysis is reasonable and supported by the best available information.

(29) Comment: Two commenters stated that the Service did not accurately consider the breadth of the economic impact that a listing would have on local communities and ranchers. The commenters argued that, despite the fact that the Service acknowledges that grazing is not a significant threat to *Lepidium papilliferum,* the practical result of a listing will be that grazing schemes will be altered, to the detriment of the landscape and the economy.

Our Response: We acknowledge that some economic impacts are a possible consequence of listing a species under the Act. However, the statute does not provide for the consideration of such impacts when making a listing decision. Section 4(b)(1)(A) of the Act specifies that listing determinations be made "solely on the basis of the best scientific and commercial data available." Such costs are, therefore, precluded from consideration in association with a listing determination. The Act provides for the consideration of potential economic impacts only in association with the designation of critical habitat.

(30) Comment: The Idaho Power Company (IPC) commented that actions the Service implements to protect *Lepidium papilliferum* could affect their ability to meet future electrical energy needs, as IPC is mandated to do, and affect ongoing operation and maintenance activities that ensure the continued delivery of electrical energy in a safe and reliable manner. In addition, IPC recommended that the Service consider a number of proposed avoidance and minimization measures when evaluating the potential effect of the Gateway West project on *L. papilliferum.*

Our Response: The IPC was not specific as to what activities will be directly impacted by the listing of *Lepidium papilliferum,* so we are unable to address these concerns; however, we are committed to working with IPC to design and manage their energy projects in ways that are compatible with the needs of the species. Listed plant and animal species receive protection under section 7 of the Act through the requirements of sections 7(a)(1) and 7(a)(2). In cases where a landowner (applicant) requests Federal agency funding or authorization for an action that may affect a listed species, as will be the case with multiple aspects of IPC's Gateway West project, the consultation requirements of section 7(a)(2) of the Act apply. Under section 7(a)(2), Federal agencies must ensure, in consultation with the Service, that any action they authorize, fund, or carry out is not likely to jeopardize the continued existence of the species.

Also, under section 7(a)(1), all Federal agencies must utilize their authorities in furtherance of the purposes of the Act by carrying out programs for the conservation of listed species. If the outcome of that consultation is a no jeopardy determination, the action can proceed as proposed. If incidental take of a listed animal species is anticipated as a result of that action, the action agency and the applicant may also have to implement specific minimization measures and reporting requirements pursuant to an Incidental Take Statement provided with the consultation. Generally, the Service also provides action agencies and applicants with conservation recommendations to minimize or avoid adverse effects of the action on a listed species. However, those recommendations are discretionary. If the outcome of the consultation is a jeopardy determination, the Service works with the action agency and applicant to revise the action in a manner that is compatible with the survival and recovery needs of the listed species and meets specific regulatory criteria that define the sideboards for those revisions. Such revisions are referred to as "reasonable and prudent alternatives," and they are provided with the intention of allowing the project to proceed, as stated above, in a manner that is compatible with the survival and recovery needs of the listed species.

The Service appreciates the efforts of Federal Action agencies and groups, such as the BLM Boise District Resource Advisory Council, in identifying additional alternatives that avoid or minimize potential impacts of proposed projects, such as the Gateway West Transmission Line Project, on *L. papilliferum.* The Service has previously completed a Conference Opinion regarding the potential effects of the proposed Gateway West Transmission Line Project on *L. papilliferum.* We will continue to work with BLM to determine if an additional section 7 conference is necessary for the updated Segments 8 and 9 routes currently being considered for the Project. Both of the updated Project segment routes continue to bisect habitat categories for *L. papilliferum.* We are also available to provide technical assistance for future renditions of the draft Mitigation and Enhancement Portfolio associated with the updated Segment 8 and 9 route locations to ensure that benefits for our trust resources, including species proposed or listed under the Endangered Species Act, are maximized.

(31) Comment: The IPC went on to state that environmental monitors will survey for and mark slickspots and aboveground populations of *Lepidium papilliferum* within 50 feet of the construction area prior to ground disturbance (including roads) in potential or occupied *L. papilliferum* habitat. No construction shall occur within 50 feet of any *L. papilliferum* plants or slickspots found by the environmental monitor. Also, construction shall not occur within 50 feet of previously known occupied *L. papilliferum* areas, based on Idaho Centers for Diseases Control data, even if aboveground plants are not observed by the environmental monitor. Within proposed critical habitat, impacts to primary constituent elements, such as native sagebrush/forb vegetation, will be avoided to the extent practicable. Seeding during reclamation in areas of suitable habitat will use methods that minimize soil disturbance such as no-till drills or rangeland drills with depth bands. Reclamation will use certified weed-free native seed. Excess soils will not be stored or spread on slickspots.

Our Response: As previously stated in our response to comment 30, the Service encourages the implementation of conservation measures that avoid or minimize adverse effects to species proposed or listed under the ESA. On September 12, 2013, the Service completed section 7 conference on the effects of the proposed Gateway West Transmission Line Project on *Lepidium papilliferum,* inclusive of the conservation measures listed by the commenter. The Gateway West Transmission Line Project Conference Opinion states that "Factors that may affect *L. papilliferum* and its habitat in the Project action area related to Project construction, operations, maintenance, and decommissioning activities include occasional damage to or loss of individual *L. papilliferum* plants (including seeds) that cannot be avoided, damage to or loss of some individual slickspot microsites that cannot be avoided, unintentional fire ignition, Project-generated dust and soil movement, removal of some remnant native vegetation, and the potential introduction or spread of invasive nonnative plants." While conservation measures incorporated into the Project design are expected to avoid or minimize some adverse effects to the species, adverse effects, including loss of habitat, are still expected to occur associated with this Project. It is uncertain to what extent the final update of Segments 8 and 9 for the Project will avoid or further minimize adverse effects to *L. papilliferum* and its proposed critical habitat.

Determination

We have carefully assessed the best scientific and commercial data available regarding the present and future threats to the species, and conclude that threatened status should be reinstated for *Lepidium papilliferum.* The plant is endemic to southwest Idaho and is limited in occurrence to an area that totals approximately 16,000 ac (6,500 ha). The species' unique slickspot habitats it requires for survival are finite and are continuing to degrade in quality due to a variety of threats. The species' limited area of occurrence makes it particularly vulnerable to the various threats affecting its specialized microsite habitats, and more than 50 percent of *L. papilliferum* EOs are already known to have been negatively affected by wildfire. The primary threats to the species are the effects of wildfire and invasive nonnative plants, especially *Bromus tectorum.* As stated in our October 8, 2009, final listing rule (74 FR 52014), we have information indicating a statistically significant negative association between *L. papilliferum* abundance and wildfire, and between *L. papilliferum* abundance and cover of *B. tectorum* in the surrounding plant community. These negative associations are consistent throughout the range of the species. Wildfire continues to affect *L. papilliferum* habitat throughout its range, and we expect this trend to continue and possibly further increase due to the projected effects of climate change. Furthermore, *B. tectorum* and other nonnative species continue to spread and degrade the sagebrush-steppe ecosystem where *L. papilliferum* persists, and we anticipate increased wildfire frequency and effects in those areas where nonnative plant species, especially *B. tectorum,* are dominant.

The best available scientific information indicates that all the significant threats described in the October 8, 2009, final listing rule (74 FR 52014) and in this new analysis, including wildfire, nonnative invasive plants, development, and habitat fragmentation, will continue and likely increase into the foreseeable future. The projected future effects of climate change will further magnify the primary threats from wildfire and *B. tectorum,* and, by association, the further expansion of Owyhee harvester ants that are positively correlated to the resulting increase in grass cover. Although conservation measures to address some of these threat factors have been thoroughly considered by the Service, effective controls to address the increased frequency of wildfire and to eradicate the expansive infestation of nonnative plants throughout the range of *Lepidium papilliferum* are not currently available, and either are not likely to be available within the foreseeable future or have not yet been shown to be sufficiently effective to offset the threats to the species to the point that it is not likely to become an endangered species within the foreseeable future.

As found in our October 8, 2009, final listing rule (74 FR 52052), we anticipate the continuation or increase of all of the significant threats to *Lepidium papilliferum* into the foreseeable future, even after accounting for ongoing and planned conservation efforts, and we find that the best available scientific data indicate that the negative consequences of these threats on the species will likewise continue or increase. Population declines and habitat degradation will likely continue in the foreseeable future to the point at which *L. papilliferum* will become in danger of extinction.

Section 3 of the Act defines an endangered species as "any species which is in danger of extinction throughout all or a significant portion of its range" and a threatened species as "any species which is likely to become an endangered species within the foreseeable future throughout all or a significant portion of its range." Because we have not yet observed the extirpation of local *Lepidium papilliferum* populations or steep declines in trends of abundance, we do not believe the species is presently in danger of extinction, and, therefore, does not meet the definition of an endangered species. However, as noted earlier, we do anticipate that *L. papilliferum* will become in danger of extinction when it reaches the point that its habitat has been so diminished that the species persists only in a small number of isolated EOs, with small populations that are fragmented from other extant populations. We conservatively estimate this point will be reached in approximately 43 to 48 years, when 80 to 90 percent of its remaining habitat will have been affected, based on the observed rates of *L. papilliferum* habitat impacted by fire, and the close association between fire and invasion by *Bromus tectorum* and other nonnative invasive plants. We can also reasonably and reliably predict that this rate will continue into the future at least until the point when no unburned habitat for the species remains, which is currently estimated at approximately 50 years.

Therefore, we conclude that 50 years represents a minimum estimate of the foreseeable future for the primary threat of wildfire. We can reasonably assume that without the unanticipated development of future effective conservation measures, the magnitude of the threats affecting *L. papilliferum* and its habitats will become progressively more severe, and that those threats, acting synergistically, are likely to result in the species becoming in danger of extinction within the next 43 to 48 years, which is within the foreseeable future as we have defined it for the species. Therefore, we conclude that, under the Act, threatened status should be reinstated for *L. papilliferum* throughout all of its range, and reaffirm its inclusion in the Federal List of Endangered and Threatened Plants.

Required Determinations

National Environmental Policy Act (42 U.S.C. 4321 et seq.)

We have determined that environmental assessments and environmental impact statements, as defined under the authority of the National Environmental Policy Act (NEPA; 42 U.S.C. 4321 *et seq.*), need not be prepared in connection with listing a species as an endangered or threatened species under the Endangered Species Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244).

Government-to-Government Relationship With Tribes

In accordance with the President's memorandum of April 29, 1994 (Government-to-Government Relations with Native American Tribal Governments; 59 FR 22951), Executive Order 13175 (Consultation and Coordination With Indian Tribal Governments), and the Department of the Interior's manual at 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. In accordance with Secretarial Order 3206 of June 5, 1997 (American Indian Tribal Rights, Federal-Tribal Trust Responsibilities, and the Endangered Species Act), we readily acknowledge our responsibilities to work directly with tribes in developing programs for healthy ecosystems, to acknowledge that tribal lands are not subject to the same controls as Federal public lands, to remain sensitive to Indian culture, and to make information available to tribes.

References Cited

A complete list of all references cited in this rule is available on the Internet at *http://www.regulations.gov.* In addition, a complete list of all references cited herein, as well as others, is available upon request from the Idaho Fish and Wildlife Office, Boise, Idaho, (see **ADDRESSES**).

Authors

The primary authors of this document are the staff members of the Idaho Fish and Wildlife Office, U.S. Fish and Wildlife Service (see **ADDRESSES**).

Authority

The authority for this action is the Endangered Species Act of 1973, as amended (16 U.S.C. 1531 *et seq.*).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Regulation Promulgation

Accordingly, we amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations, as follows:

PART 17—ENDANGERED AND THREATENED WILDLIFE AND PLANTS

■ 1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 1531–1544; 4201–4245; unless otherwise noted.

■ 2. Amend § 17.12(h) by adding the following entry to the List of Endangered and Threatened Plants in alphabetical order under Flowering Plants:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Scientific name	Common name	Where listed	Status	Listing citations and applicable rules
Flowering Plants				
*	*	*	*	* * *
Lepidium papilliferum	Slickspot peppergrass	Wherever found	T	74 FR 52013; 10/8/2009 81 FR [*Insert* **Federal Register** *page where the document begins*]; 8/17/2016
*	*	*	*	* * *

* * * * *

Dated: May 31, 2016.

Stephen Guertin,

Acting Director, U.S. Fish and Wildlife Service.

[FR Doc. 2016–19528 Filed 8–16–16; 8:45 am]

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Part V

Department of Health and Human Services

42 CFR Part 88
World Trade Center Health Program; Amendments to Definitions, Appeals, and Other Requirements; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 88

[Docket No. CDC–2016–0072; NIOSH–291]

RIN 0920–AA56

World Trade Center Health Program; Amendments to Definitions, Appeals, and Other Requirements

AGENCY: Centers for Disease Control and Prevention, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: In 2011 and 2012, the Secretary, Department of Health and Human Services (HHS), promulgated regulations designed to govern the World Trade Center (WTC) Health Program (Program), including the processes by which eligible responders and survivors may apply for enrollment in the Program, obtain health monitoring and treatment for WTC-related health conditions, and appeal enrollment and treatment decisions, as well as a process to add new conditions to the List of WTC-Related Health Conditions. After using the regulations for a number of years, the Administrator of the WTC Health Program has identified potential improvements to certain existing provisions, including, but not limited to, appeals of enrollment, certification, and treatment decisions, as well as the procedures for the addition of health conditions for WTC Health Program coverage. He has also identified the need to add new regulatory provisions, including, but not limited to, standards for the disenrollment of a WTC Health Program member and decertification of a certified WTC-related health condition.

DATES: The Administrator of the WTC Health Program invites comment on this proposed rule from interested parties. Comments must be received by September 16, 2016.

ADDRESSES: Interested parties may submit comments by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* NIOSH Docket Office, 1090 Tusculum Avenue, MS C–34, Cincinnati, OH 45226–1998.

Instructions: All submissions received should include the agency name (Centers for Disease Control and Prevention, HHS) and docket number (CDC–2016–0072; NIOSH–291) or Regulation Identifier Number (0920–AA56) for this rulemaking. All relevant comments, including any personal information provided, will be posted without change to *http://www.regulations.gov.* For detailed instructions on submitting public comments, see the "Public Participation" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents, go to *http://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Rachel Weiss, Program Analyst; 1090 Tusculum Ave, MS: C–46, Cincinnati, OH 45226; telephone (855) 818–1629 (this is a toll-free number); email *NIOSHregs@cdc.gov.*

SUPPLEMENTARY INFORMATION: This preamble is organized as follows:

I. Executive Summary
  A. Purpose of Regulatory Action
  B. Summary of Major Provisions
  C. Costs
II. Public Participation
III. Background
  A. History and Scope of Rulemaking
  B. WTC Health Program Statutory Authority
IV. Summary of Proposed Rule
V. Regulatory Assessment Requirements
  A. Executive Order 12866 and Executive Order 13563
  B. Regulatory Flexibility Act
  C. Paperwork Reduction Act
  D. Small Business Regulatory Enforcement Fairness Act
  E. Unfunded Mandates Reform Act of 1995
  F. Executive Order 12988 (Civil Justice)
  G. Executive Order 13132 (Federalism)
  H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)
  I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)
  J. Plain Writing Act of 2010

I. Executive Summary

A. Purpose of Regulatory Action

The Secretary, HHS, promulgated regulations designed to implement the WTC Health Program in a 2011 interim final rule establishing Part 88 in Title 42 of the Code of Federal Regulations,[1] and in a 2012 final rule adding procedures for the submission of petitions to add health conditions for Program coverage.[2] These regulations in 42 CFR part 88 include the processes by which eligible responders and survivors may apply for enrollment in the WTC Health Program, obtain health monitoring and treatment for WTC-related health conditions, and appeal enrollment and treatment decisions. The Administrator of the WTC Health Program (Administrator) has determined that amending some provisions in Part 88 and adding others will benefit both the WTC Health Program and its members by clarifying requirements and improving administrative processes.

B. Summary of Major Provisions

Although the Administrator proposes to amend a number of existing sections in part 88, many of the changes would be non-substantive. Some existing language would be moved into new sections for clarity. Substantive amendments would be made to the following existing provisions:

- *§ 88.11 Appeals regarding eligibility determinations—responders and survivors*—this section would be amended to clarify appeal procedures and to allow the Administrator to make a final decision on the appeal.
- *§ 88.15 Appeals regarding treatment*—this section would be significantly modified to clarify the appeal process, including allowing a WTC Health Program member or his/her designated representative to submit new evidence in support of the appeal and make an oral statement to the Federal Official reviewing the case, and allow the Administrator to make a final decision on the appeal.
- *§ 88.17 Addition of health conditions to the list of WTC-related health conditions*—this section would be amended to extend the deadline for the Administrator's response to a petition for the addition of a health condition from 60 to 90 calendar days, consistent with current law. Another amendment to this section would allow the Administrator to consider a petition to be invalid if it presents the same scientific evidence supporting the addition of the health condition that was previously considered by the Administrator in a response published in the **Federal Register**.

New language on the following topics would be added to Part 88:

- *Disenrollment*—this new section would describe the WTC Health Program's procedures for disenrolling a Program member and the circumstances under which disenrollment would be applicable.
- *Decertification*—this new section would describe the WTC Health Program's ability to decertify a WTC-related health condition or health condition medically associated with a WTC-related health condition and the circumstances under which decertification would be applicable.
- *Appeal of reimbursement denial*—this new section would clarify the statutory appeal right for Program medical providers in cases in which the WTC Health Program has denied

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[1] 76 FR 38914 (July 1, 2011).

[2] 77 FR 24628 (Apr. 25, 2012).

reimbursement for treatment found not to be medically necessary.

- *Coordination of benefits and recoupment*—this new section would be added to reflect the statutory requirement that payment for treatment, including pharmaceuticals, must be reduced or recouped as appropriate when the WTC Health Program finds that payment has been made by workers' compensation, public, or private health insurance.

C. Costs

This rulemaking is expected to result in approximately $42,742 in costs to the WTC Health Program associated with updating existing Program policies and developing new policies in accordance with amendments proposed in this action.

II. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, opinions, recommendations, and/or data. Comments are invited on any topic related to this proposed rule. Comments received, including attachments and other supporting materials, are part of the public record and subject to public disclosure. Any information in the comment or supporting materials considered confidential or inappropriate for public disclosure should not be included.

Comments submitted electronically or by mail should be titled "Docket No. CDC–2016–0072" and should identify the author(s) and contact information in case clarification is needed. Electronic and written comments can be submitted to the addresses provided in the **ADDRESSES** section, above. All communications received on or before the closing date for comments will be fully considered by the Administrator of the WTC Health Program.

III. Background

This action proposes to amend certain regulatory provisions established in Part 88 of Title 42 of the Code of Federal Regulations and add new provisions to the part.

A. History and Scope of Rulemaking

On July 1, 2011, HHS published an interim final rule (July 2011 IFR) to establish Part 88 in Title 42 of the Code of Federal Regulations and implement the WTC Health Program as administered by the Director of the National Institute for Occupational Safety and Health (NIOSH) (76 FR 38914). Provisions established in Part 88 include the following: WTC Health Program definitions; general provisions; eligibility and application requirements for WTC responders and screening- and certified-eligible survivors; initial health evaluations for screening-eligible survivors; enrollment, certification, and treatment appeals; physician determinations; the process for certifying WTC-related health conditions; the medical necessity standard; and reimbursement for health care providers.

A section describing the process for adding new health conditions to the List of WTC-Related Health Conditions (List) was finalized on April 25, 2012 (77 FR 24628).

Regulations establishing the eligibility criteria for Shanksville, Pennsylvania and Pentagon responders were established in an interim final rule published on March 28, 2013 (78 FR 18855).

Certain types of cancer, including rare cancers and childhood cancers, were added to the List in a September 12, 2012 final rule (77 FR 56138). Another cancer rulemaking, adding prostate cancer to the List, was finalized on September 19, 2013 (78 FR 57505). An IFR was published on February 18, 2014 (February 2014 IFR) to clarify the definition of "childhood cancers" and revise the definition of "rare cancers" (79 FR 9100). As a result of this IFR, cancers of the brain, the pancreas, and the testes, and invasive cervical cancer are also considered covered conditions.

Finally, on September 11, 2015, a notice of proposed rulemaking (NPRM) was published proposing the addition of new-onset chronic obstructive pulmonary disease (COPD) and WTC-related acute traumatic injury to the List (80 FR 54746). A final rule adding the two health conditions to the List was published on July 5, 2016 (81 FR 43510).

Regulatory text promulgated through an IFR, such as Part 88, is effective prior to the consideration of public comments and may be amended just as if it had been promulgated by normal notice-and-comment rulemaking. In this proposed rule, the Administrator proposes amendments to certain sections of Part 88, responds to public comments on those sections received in response to the July 2011 IFR and the February 2014 IFR, and seeks public comment on the amendments proposed in this notice.

This NPRM and all of the interim final rules described above,[3] as well as any public comments to any of the interim final rules not addressed in this NPRM, will be addressed in a final rule.

B. WTC Health Program Statutory Authority

Title I of the James Zadroga 9/11 Health and Compensation Act of 2010 (Pub. L. 111–347, as amended by Pub. L. 114–113), added Title XXXIII to the Public Health Service Act (PHS Act), establishing the WTC Health Program within HHS. The WTC Health Program provides medical monitoring and treatment benefits to eligible firefighters and related personnel, law enforcement officers, and rescue, recovery, and cleanup workers who responded to the September 11, 2001, terrorist attacks in New York City, at the Pentagon, and in Shanksville, Pennsylvania (responders), and to eligible persons who were present in the dust or dust cloud on September 11, 2001, or who worked, resided, or attended school, childcare, or adult daycare in the New York City disaster area (survivors).

All references to the Administrator of the WTC Health Program (Administrator) in this notice mean the WTC Program Administrator, the Director of NIOSH, or his or her designee. Section 3301(j) of the PHS Act authorizes the Administrator to promulgate such regulations as are necessary to administer the WTC Health Program.

IV. Summary of Proposed Rule

The Administrator finds it necessary to amend certain existing sections of 42 CFR part 88, to rearrange others, and to add new sections. The rationales for each proposed amendment are offered below, along with summaries of the proposed rule text. This action answers only those public comments relevant to the provisions that the Administrator is proposing to amend in this action.

The Administrator proposes to amend the title of certain Part 88 sections referenced below; the new titles used in the preamble correspond with the proposed regulatory text found at the end of this document.

The table below matches the proposed reorganization of Part 88 with the originating sections in the existing regulation. No changes are proposed to §§ 88.3 and 88.7; although they are included in the table for completeness, they are not referenced again in this notice. The regulatory text with proposed amendments is found in the last section of this notice.

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[3] These include the July 2011 IFR (establishing Part 88 and implementing the Program), the March 2013 IFR (establishing eligibility criteria for Shanksville and Pentagon responders), and the February 2014 IFR (clarifying the definition of "childhood cancers" and revising the definition of "rare cancers").

PROPOSED REORGANIZATION AND SECTION TITLE AMENDMENTS

Proposed section	Originating section
88.1 Definitions	88.1 Definitions.
88.2 General provisions	88.2 General provisions.
88.3 Eligibility—currently-identified responders*	88.3 Eligibility—currently-identified responders.
88.4 Eligibility criteria—WTC responders	88.4 Eligibility criteria—status as a WTC responder.
88.5 Application process—WTC responders	88.5 Application process—status as a WTC responder.
88.6 Enrollment decision—WTC responders	88.6 Enrollment determination—status as a WTC responder.
88.7 Eligibility—currently-identified survivors *	88.7 Eligibility—currently-identified survivors.
88.8 Eligibility criteria—WTC survivors	88.8 Eligibility criteria—status as a WTC survivor.
88.9 Application process—WTC survivors	88.9 Application process—status as a WTC survivor.
88.10 Enrollment decision—screening-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.11 Initial health evaluation for screening-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.12 Enrollment decision—certified-eligible survivors	88.10 Enrollment determination—status as a WTC survivor.
88.13 Disenrollment	New.
88.14 Appeal of enrollment or disenrollment decision	88.11 Appeals regarding eligibility determinations—responders and survivors.
88.15 List of WTC-Related Health Conditions	relocated from 88.1.
88.16 Addition of health conditions to the List of WTC-Related Health Conditions.	88.17 Addition of health conditions to the list of WTC-related health conditions.
88.17 Physician's determination of WTC-related health conditions	88.12 Physician's determinations of WTC-related health conditions.
88.18 Certification	88.13 WTC Program Administrator's certification of health conditions.
88.19 Decertification	New.
88.20 Authorization of treatment	88.14 Standard for determining medical necessity.
88.21 Appeal of certification, decertification, or treatment authorization decision.	88.15 Appeals regarding treatment.
88.22 Reimbursement for medical treatment and services	88.16 Reimbursement for medically necessary treatment, outpatient prescription pharmaceuticals, monitoring, and initial health evaluations, and travel expenses.
88.23 Appeal of reimbursement denial	New.
88.24 Coordination of benefits and recoupment	New.
88.25 Reopening of WTC Health Program final decisions	88.11 Appeals regarding eligibility determinations—responders and survivors and 88.15 Appeals regarding treatment.

* No amendments are proposed for this section.

Section 88.1 Definitions

The Administrator established definitions of the terms commonly used in the WTC Health Program in 42 CFR 88.1. For reasons discussed below, amendments are proposed to the definitions of the following terms: "Act," "Certification," "Certified-eligible survivor," "Clinical Center of Excellence," "List of World Trade Center (WTC)-related health conditions," "Medically necessary treatment," "Nationwide provider network," "World Trade Center (WTC) Health Program," "World Trade Center (WTC) Program Administrator," "World Trade Center (WTC)-related health condition," and "World Trade Center (WTC)-related musculoskeletal disorder." New definitions of "World Trade Center (WTC) Health Program member" and "World Trade Center (WTC)-related acute traumatic injury," would also be added.

Act

The Administrator proposes to amend the current definition of "Act" to reference the 2016 reauthorization of the WTC Health Program in Public Law 114–113.

Certification

The Administrator proposes to amend the current definition of "certification" to better characterize the role of certification in the WTC Health Program. Certification would mean the WTC Health Program review and approval of a health condition as eligible for medically necessary treatment. A certified WTC-related health condition or a certified health condition medically associated with a certified WTC-related health condition is eligible for medically necessary treatment in the WTC Health Program.

Certified-Eligible Survivor

The current definition of "certified-eligible survivor" references enrollment of certified-eligible survivors under § 88.10(f). This reference is incorrect and, in any event, should be amended to reflect the reorganization of Part 88 in this action, placing the enrollment of certified-eligible survivors in § 88.12(b).

Clinical Center of Excellence (CCE)

The Administrator proposes to amend the current definition of "Clinical Center of Excellence" to add the acronym "CCE." An amendment to paragraph (2) would strike reference to certified-eligible survivors and indicate that a CCE may include health care providers who have received WTC Health Program training, as described in the PHS Act.[4] The term "WTC Program Administrator" is replaced with "Administrator of the WTC Health Program" in paragraph (4) of this definition.

List of WTC-Related Health Conditions

The Administrator proposes non-substantive amendments to the existing definition of "List of World Trade Center (WTC)-related health conditions" (List) to allow for easier reference to the health conditions covered by the WTC Health Program, to simplify future amendments to the List, and to give the List more prominence by moving it into its own section. The term "List of WTC-

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[4] *See* PHS Act, sec. 3305(b)(1)(A)(ii).

Related Health Conditions" would be capitalized to reflect common usage by the Program. Furthermore, the Administrator proposes to move the List from the § 88.1 Definitions section to a new § 88.15. The definition of "List of WTC-related health conditions" would be replaced in the § 88.1 Definitions section with a marker to point the reader to the new § 88.15.

Medically Necessary Treatment

The Administrator proposes to amend the existing definition of "medically necessary treatment" to add the term "WTC Health Program members" to clarify that the standard applies to the provision of health care services to a particular member. The definition would also be amended to indicate that the medical treatment protocols are also developed with input from the CCEs. This language would be added to reflect the language in section 3305(a)(2)(A)(vi) of the PHS Act.

Nationwide Provider Network

The existing definition of "Nationwide provider network" would be slightly amended to capitalize the name Nationwide Provider Network and include the acronym "NPN."

World Trade Center (WTC) Health Program

The Administrator proposes to amend the existing definition of "World Trade Center (WTC) Health Program" to update the reference to the authorizing statute, Title XXXIII of the Public Health Service Act as amended, 42 U.S.C. 300mm to 300mm-61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111–347, as amended by Pub. L. 114–113).

World Trade Center (WTC) Health Program Member

The Administrator proposes to add a new definition for the term "World Trade Center (WTC) Health Program member." This term is often used in Program publications and refers generally to any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program. The phrase "responder, screening-eligible survivor, or certified-eligible survivor" is replaced with "WTC Health Program member" as appropriate in this Part.

World Trade Center (WTC) Program Administrator

The Administrator proposes to amend the existing definition of "WTC Program Administrator" to clarify the title and to allow flexibility in how the Administrator is addressed in WTC Health Program documents. This non-substantive amendment to the existing definition would allow the use of the identical terms "Administrator of the WTC Health Program" and "Administrator."

World Trade Center (WTC)-Related Acute Traumatic Injury

The Administrator proposes to add "WTC-related acute traumatic injury" to direct the reader to the List of WTC-Related Health Conditions in 42 CFR 88.15.

World Trade Center (WTC)-Related Health Condition

"World Trade Center (WTC)-related health condition" would be amended to clarify that WTC-related health conditions are those that are found in the WTC Health Program regulations. The Administrator has added new health conditions to the statutory list, found in sections 3312 and 3322 of the PHS Act, through rulemaking; [5] the expanded List is currently codified in § 88.1 of Part 88. Because the Administrator is proposing to move the List from § 88.1 to § 88.15, amendments to this definition would direct the reader to its location.

World Trade Center (WTC)-Related Musculoskeletal Disorder

The Administrator proposes to amend the existing definition of "WTC-related musculoskeletal disorder" to direct the reader to the List of WTC-Related Health Conditions in 42 CFR 88.15.

Section 88.2 General Provisions

This existing section establishes the appointment process for an applicant's or WTC Health Program member's designated representative and the parameters of the representative's authority. In response to public comments submitted to the July 2011 IFR docket regarding this section,[6] the Administrator declines to amend this section to add "organization" to the types of eligible representatives in paragraph (a) or to allow the designation of an alternate representative. Only one individual at a time is permitted to be the designated representative; if the applicant or member wishes to select a different representative, he or she may do so by notifying the WTC Health Program in writing, signed by the applicant or member and either submitted in hard copy or scanned and submitted electronically, of the intent to withdraw the previous representative and name a new one. Accordingly, the Administrator proposes to amend paragraph (a)(2) of this section to clarify that a designated representative must be withdrawn in writing. Paragraph (a)(3) would be amended to clarify that the designated representative may represent the WTC Health Program member on any other administrative matter, in addition to eligibility and certification matters. Paragraph (a)(4) would be amended to indicate that an applicant or Program member may designate a representative unless that individual's service is prohibited by law, WTC Health Program policies and procedures, or contract provisions.

Finally, because of proposed amendments to existing § 88.16, the Administrator would move provisions regarding reimbursement for transportation and travel expenses into reserved paragraph (b).

Section 88.4 Eligibility Criteria—WTC Responders

This section title would be amended from "Eligibility criteria—status as a WTC responder" to the title above, for clarity.

Section 88.5 Application Process—WTC Responders

This section title would be amended from "Application process—status as a WTC responder" to the title above, for clarity.

Section 88.6 Enrollment Decision—WTC Responders

This section title would be amended from "Enrollment determination—status as a WTC responder" to the title above, for clarity. The Administrator also finds that the term "determination" or "determine" should be replaced with "decision" or "decide" in this section and throughout Part 88 where the text refers to a WTC Health Program action. Although these terms were used interchangeably in the July 2011 IFR, the word "determination" is used in the Program to describe the finding made by a CCE or NPN physician that a member's diagnosed health condition meets the PHS Act standards to be considered a WTC-related health condition or a health condition medically-associated with a WTC-related health condition; such determination is submitted to the Administrator for a certification decision (*see* § 88.18). Finally, language in existing paragraph (c)(2)(i) and

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[5] *See* final rule, 77 FR 56138 (Sept. 12, 2012) (adding certain types of cancer); final rule, 78 FR 57505 (Sept. 19, 2013) (adding prostate cancer); interim final rule, 79 FR 9100 (Feb. 18, 2014) (clarifying the definition of "childhood cancers" and revising the definition of "rare cancers"); and final rule, 81 FR 43510 (July 5, 2016) (adding new-onset chronic obstructive pulmonary disease and WTC-related acute traumatic injury).

[6] NIOSH Docket 235, CDC–2011–0009.

(c)(2)(i)(A) would be consolidated into one paragraph at (c)(2)(i).

Section 88.8 Eligibility Criteria—WTC Survivors

This section title would be amended from "Eligibility criteria—status as a WTC survivor" to the title above, for clarity.

Section 88.9 Application Process—WTC Survivors

This section title would be amended from "Application process—status as a WTC survivor" to the title above, for clarity.

Section 88.10 Enrollment Decision—Screening-Eligible Survivors

The Administrator proposes to simplify the existing provisions in § 88.10, titled "Enrollment determination—status as a WTC survivor," by splitting the section into three separate sections: Enrollment decision—screening-eligible survivors; initial health evaluation for screening-eligible survivors; and enrollment decision—certified-eligible survivors. The screening-eligible survivor status decision provisions would remain in § 88.10; the initial health evaluation provisions would be moved into a new § 88.11, and the certified-eligible survivor status provisions would be moved into a new § 88.12.

For the reasons discussed above, the Administrator proposes to amend the title of this existing section from "Enrollment determination—status as a WTC survivor" to "Enrollment decision—screening-eligible survivors." The new title would clarify that enrollment "decisions" are made by the WTC Health Program, to avoid confusion with "determinations" made by CCE and NPN physicians regarding a member's health condition. Amendments to this section would retain and combine the substance of existing paragraphs (a), (b), and (c) into new paragraphs (a) and (b). Proposed revisions to the language concerning the 60-day deadline for the WTC Health Program's decision would clarify that the date would be calculated in calendar days and extend the notification deadline to be no later than 60 days of receipt of the application, rather than the date of transmission of the application, which can be difficult to determine. The 60-day notification deadline would be tolled while the applicant is correcting deficiencies in the application or supporting documents. Existing paragraph (d), described below, would be removed to a new § 88.11. Existing paragraphs (e), (f), and (g), described below, would be removed to a new § 88.12.

Section 88.11 Initial Health Evaluation for Screening-Eligible Survivors

A new § 88.11 comprises language formerly found in § 88.10(d). Minor amendments to this new section would include replacing "diagnoses" with "determines" to align the rule text with terms commonly used by the WTC Health Program.

In response to public comments submitted to the July 2011 IFR docket regarding these provisions,[7] the Administrator declines to allow a screening-eligible survivor to obtain an additional health evaluation at no cost or to specify that the cost of an additional evaluation would be the same as is paid by the WTC Health Program. The Administrator is constrained by section 3321(b)(3) of the PHS Act, which explicitly limits screening-eligible survivors to a single initial health evaluation at no cost. The member could request more than one health evaluation, but the Administrator has no legal obligation or authority to pay for subsequent health evaluations. The Administrator does not propose any substantive changes to this text.

Section 88.12 Enrollment Decision—Certified-Eligible Survivors

A new § 88.12 would comprise the former § 88.10(e), describing certification determinations; § 88.10(f), describing denials of certification; and § 88.10(g), describing notification of the certified-eligible survivor status decision. The new title would clarify that enrollment "decisions" are made by the WTC Health Program, to avoid confusion with "determinations" made by CCE or NPN physicians regarding a member's health condition. Proposed amendments to this new section would include removing redundant language and clarifying certification status language. Existing language in § 88.10(e) states that "[i]f the individual's condition is certified as a WTC-related health condition, the individual will also be certified as a certified-eligible survivor." The use of "also" may incorrectly suggest the WTC Health Program member retains two statuses, as both a screening-eligible and a certified-eligible survivor, simultaneously. Amendments would clarify that if the Program member's condition is certified as a WTC-related health condition, the member's status will automatically change to that of a certified-eligible survivor. The Administrator does not propose any substantive changes to this text.

Section 88.13 Disenrollment

The Administrator proposes to add a new section to Part 88 to clarify the process for disenrolling a member from the WTC Health Program. To date, only 12 enrolled members have been found to have been wrongly enrolled due to Program error or inaccurate eligibility information. Allowing individuals who do not meet WTC Health Program enrollment eligibility criteria to stay in the Program may result in those individuals improperly receiving medical benefits. Moreover, individuals who are erroneously enrolled may fill the statutory limits on the number of WTC responders and certified-eligible survivors enrolled in the WTC Health Program,[8] thereby preventing qualified individuals from enrolling.

Pursuant to this section, a WTC Health Program member enrolled pursuant to § 88.4 or § 88.8 may be disenrolled if the member did not provide sufficient proof of eligibility and was mistakenly enrolled in the Program, or the member's location, activities, and/or duration are inconsistent with the eligibility criteria for newly enrolled WTC responders or screening-eligible survivors; additionally, a member may be disenrolled if his or her enrollment was based on inaccurate or fraudulent information. A member may be disenrolled following a periodic audit conducted by the Program to ensure that enrollment decisions are proper or when the Program is made aware of new information that would impact the enrollment decision. A member could also choose to disenroll from the Program at his or her own discretion.

A member who has been disenrolled from the WTC Health Program would be notified in writing of the disenrollment decision and given the opportunity to appeal that decision, within 90 days of the date of the Administrator's notification letter, in accordance with § 88.14. Finally, a member who is disenrolled may reapply for enrollment in the WTC Health Program if new information is available to support the application.

Section 88.14 Appeal of Enrollment or Disenrollment Decision

This section establishes procedures for the appeal of a WTC Health Program decision to deny enrollment to an applicant or disenroll a Program member. The Administrator proposes to amend the section heading from

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[7] NIOSH Docket 235, CDC–2011–0009.

[8] *See* PHS Act, secs. 3311(a)(4) and 3321(a)(3).

"Appeals regarding eligibility determinations—responders and survivors" to "Appeal of enrollment or disenrollment decision," to provide greater clarity.

The Administrator has identified the need to make substantive amendments to this existing section due to other proposed revisions in this notice and in response to public comment on the July 2011 IFR.[9] Commenters asserted that the existing 60-day deadline for filing an appeal of an enrollment denial is too short and requested that applicants be given from 180 days to a year to file an appeal. The Administrator agrees that the current requirement that an applicant file an appeal within 60 days of the date on the notification letter explaining the enrollment denial may not provide enough time for the applicant to gather necessary documentation or other information for the appeal. Therefore, the Administrator proposes amendments to this section to permit consideration of a denied applicant's appeal letter that is postmarked[10] within 90 calendar days of the date of the Administrator's denial notification letter. The Administrator similarly finds that allowing 90 days for submission of an appeal request subsequent to a disenrollment of a Program member should allow ample time for a disenrolled Program member to gather any necessary information. However, the Administrator requests further public comment on the appropriateness of allowing 90 days for appeal of a disenrollment decision.

The Administrator also proposes to amend this section to recognize appeals of a WTC Health Program decision to disenroll a Program member, as described in the proposed new disenrollment provisions in § 88.13.

Because of the reorganization of this part, the current number of this section, § 88.11, would be changed to § 88.14. Existing paragraph (b) would be redesignated paragraph (c). New language for paragraph (b) would establish the appeal request process and mirror the appeal process for certification, decertification, and treatment authorization decisions in § 88.21. The new language would specify that an appeal request must be made in writing, identify the denied applicant or disenrolled Program member and the designated representative, if any, and state the reasons why the WTC Health Program's action was incorrect and should be reversed. As currently permitted, the appeal request may include relevant new information not previously considered by the Program. Existing paragraph (c), which allows the Administrator to reopen and reconsider an enrollment denial, would be removed from this section and placed in a new section, § 88.25 described below, regarding reopenings generally. A new paragraph (c) would describe the appeal process, which would consist of the appointment of a Federal Official, who will be an HHS employee independent of the WTC Health Program, to review the case and submit a recommendation to the Administrator.

Finally, a new paragraph (d) would change the existing appeal process to result in the Federal Official making a recommendation to the Administrator, who would then make a final decision on the appeal. This paragraph would also clarify that the Administrator will share the results of the Federal Official's review and any administrative actions taken by the WTC Health Program with the denied applicant, disenrolled Program member, or designated representative who filed the appeal. The Administrator declines to offer a deadline for the final decision on an enrollment appeal, as requested by public comment on the July 2011 IFR.[11] Given the potentially complex nature of appeals decisions, the Administrator is concerned that limiting the amount of time available to the Federal Official and/or the Administrator to review the denied applicant's or disenrolled Program member's file (including any new information submitted) could result in undue burden on the Federal Official and/or Program staff and not allow for a thorough review of the appeal. In the Program's experience, final decisions on enrollment appeals typically occur within 45 days of receipt of the applicant's appeal request.

Section 88.15 List of WTC-Related Health Conditions

This new section contains the health conditions enumerated in the PHS Act at sections 3312(a)(3) and 3322(b) as well as those additional WTC-related health conditions promulgated through rulemaking by the Administrator.[12] The Administrator proposes moving the List of WTC-related health conditions from § 88.1, the definitions section, to a new § 88.15 in order to better clarify and emphasize for stakeholders the conditions that are covered by the WTC Health Program. The Administrator also proposes to capitalize the section title as well as the name "List of WTC-Related Health Conditions," as it appears throughout Part 88, to reflect the terminology commonly used in most Program publications. The health conditions that would be included in this new section are the same health conditions named in the definition, "List of WTC-related health conditions" currently found in § 88.1. The reference to "interstitial lung disease" in paragraph (a)(1) should be plural and would be corrected in this action, the reference to "upper airway hyperreactivity" in paragraph (a)(7) is misspelled in the current regulation and would be corrected in this action, and the acronym "PTSD" would be added to the existing WTC-related health condition, "Posttraumatic stress disorder" in (b)(1).

The definition of "WTC-related musculoskeletal disorder," also currently found in § 88.1, would be incorporated into paragraph (c) of the new § 88.15. No other substantive changes to the rule text regarding the List are proposed.

In response to the July 2011 IFR, one commenter requested that 'musculoskeletal disorders' be available to survivors for certification.[13] The PHS Act limits the coverage of musculoskeletal disorders to responders to the terrorist attacks in New York City. The same commenter requested the addition of "developmental disorders and any disorder linked specifically to children's WTC exposures, including those that occurred in utero." Individuals who were children at the time of the terrorist attacks may be considered survivors if they meet the eligibility criteria for screening- or certified-eligible survivors. Health conditions cannot be added to the List without rulemaking, supported by scientific or medical evidence, pursuant to the PHS Act and procedures established under Part 88 for adding new WTC-related health conditions to the List.

Public comments submitted to the docket for the February 2014 IFR (clarifying the definition of "childhood cancers" and revising the definition of "rare cancers") relevant to this section[14] are addressed here, including questions regarding the availability of a list of rare cancers identified by the Program, and requests that the WTC Health Program reach out to members who were denied certification of brain and pancreatic cancers prior to publication of the February 2014 IFR.[15] The WTC Health Program published a list of the cancers considered rare on the Policies & Procedures Web page;[16] the full list of cancer types covered by the Program is found on the List of WTC-Related Health Conditions. Further, when a new health condition is added to the List or when WTC Health Program policy regarding a condition on the List changes, it is Program practice to communicate directly with members or their CCE or NPN regarding conditions previously denied certification, to determine if the condition should be re-evaluated for certification. No amendments to the List are proposed in response to public comment.

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[9] NIOSH Docket 235, CDC–2011–0009.

[10] For appeal letters submitted electronically via fax or email, the date of the electronic transmission is understood to be the date the letter is 'postmarked.'

[11] NIOSH Docket 235, CDC–2011–0009.

[12] *See supra* note 5.

[13] NIOSH Docket 235, CDC–2011–0009.

[14] NIOSH Docket 268, CDC–2014–0004.

Section 88.16 Addition of Health Conditions to the List of WTC-Related Health Conditions

A new § 88.16 would comprise language formerly found in § 88.17. This section establishes the process for adding a new health condition to the List of WTC-Related Health Conditions in § 88.15. The Administrator has determined that these existing provisions should be revised to clarify the circumstances under which the Administrator is required to consider a new submission requesting the addition of a health condition that has been previously considered. Amending this section would promote administrative efficiency by not requiring WTC Health Program staff to devote time to reviewing and responding to a submission that, in substance, was already considered.

The Administrator proposes to change the number of this existing section from § 88.17 to § 88.16. The Administrator further proposes minor amendments to clarify that the List would be moved to § 88.15 and to replace "determination" with "decision," as explained above. Paragraph (a) describes the criteria for a valid petition, including the following: An explicit statement of an intent to petition; the name, contact information, and signature of the petitioning party; the name and/or description of the condition(s) to be added; and the reasons for adding the condition(s), including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition(s) to be added. The paragraph would be amended to clarify that the Administrator accepts all submissions from interested parties and then evaluates the submissions to decide whether they are valid petitions. Paragraph (a)(1) would be amended slightly to clarify in paragraph (a)(1)(i) that the petition must state an intent to petition the Administrator to add a health condition to the List. Paragraph (a)(1)(ii) would be amended to require that the petitioner provide a signature on the petition. Requiring a signature aligns the regulation with the petition form offered by the Program, which requires that the petitioner provide a signature. Paragraph (a)(1)(iii) would be amended to indicate that a petitioner may include either the name "and/or" a description of the petitioned health condition.

Paragraph (a)(2) would be amended to state that the Administrator will take one of the available actions within 90 calendar days after receipt of a valid petition, including requesting a recommendation from the WTC Health Program Scientific/Technical Advisory Committee (STAC) or publishing a notice in the **Federal Register**. The window for administrative action following receipt of a petition was extended from 60 to 90 days in the recent amendments to the PHS Act.[17] Each petition and corresponding **Federal Register** notice is published on the WTC Health Program Web site.

Existing paragraph (a)(3) would be redesignated (a)(4), and new text in paragraph (a)(3) would allow the 90-day deadline to be tolled while the Administrator seeks more information from the interested party regarding an unclear submission.

Because of the preceding change, existing paragraph (a)(4) is redesignated (a)(5), and proposed amendments would clarify the handling of a submission that requests the addition of a health condition previously evaluated for addition to the List by the WTC Health Program. In such a case, if the submission does not include a new medical basis for an association between the health condition and 9/11 exposures and is received after the publication of a response to an earlier petition in the **Federal Register**, then the submission would not be considered a valid petition and would not be answered in the **Federal Register**. The submitter would be provided an explanation of the Program's decision in writing.

The Administrator proposes to amend paragraph (b) to identify the proposed new location of the List of WTC-Related Health Conditions as a separate section in Part 88. Other amendments to paragraph (b) would incorporate additional PHS Act amendments extending the respective deadlines for the submission of the STAC's recommendation, when requested, and the subsequent publication of the Administrator's decision from 60 to 90 calendar days.[18] Paragraph (b)(1) would be amended to update those deadlines and clarify that all deadlines will be calculated in terms of calendar days. A new paragraph (b)(2) would reflect the recent amendments to the PHS Act requiring the Administrator to provide for an independent peer review of the scientific and technical evidence that would be the basis for adding a health condition to the List.[19]

Section 88.17 Physician's Determination of WTC-Related Health Conditions

A new § 88.17 would comprise language formerly found in § 88.12. This section establishes the basis for a CCE or NPN-affiliated physician's determination that a WTC Health Program member has a health condition that can be certified and covered by the WTC Health Program.

The Administrator finds it important to clarify the statutory standard for a physician's determination that a health condition is WTC-related or medically associated with a WTC-related health condition. The language of this existing section requires simply that a physician communicate the "basis for the diagnosis" to the WTC Health Program; the Program then decides whether to certify the health condition for treatment. The Administrator proposes to amend this section to incorporate statutory language requiring that the basis for a physician's determination be a finding that 9/11 exposure is "substantially likely" to be a "significant factor in aggravating, contributing to, or causing the illness or health condition." Although the WTC Health Program has not documented any problems with interpretation of the existing rule text, the Administrator thinks that inclusion of the statutory standard would clarify for stakeholders what the physician is required to establish before requesting certification of a health condition or medically associated health condition. This amendment would have no impact on the Program or its members.

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[15] This interim final rule amended the List of WTC-Related Health Conditions to reverse the policy of considering cancers of the brain and the pancreas ineligible for Program coverage, clarified the definition of "childhood cancers," and revised the definition of "rare cancers" (79 FR 9100). As a result of the IFR, cancer of the brain, the pancreas, the testes, and invasive cervical cancer are considered eligible for coverage in the Program.

[16] *See* John Howard, Administrator of the WTC Health Program, *Rare Cancers*, May 5, 2014, *http://www.cdc.gov/wtc/pdfs/WTCHP_PP_RareCancers05052014.pdf.*

[17] *See* Public Law 111–347, as amended by Public Law 114–113, PHS Act, sec. 3312(a)(6)(B)–(C).

[18] PHS Act, sec. 3312(a)(6)(C).

[19] PHS Act, sec. 3312(a)(6)(F).

Because of proposed amendments to earlier sections, the original number of this section, § 88.12, would be changed to § 88.17. "Shall" would be replaced with "must."

Public comments submitted to the July 2011 IFR docket on this section[20] included a request to specify that a physician's determination must be transmitted to the Administrator "promptly, but in no case longer than 30 days from the initial clinical visit." The Administrator declines to establish such a deadline because doing so may unduly burden the physician. No amendments to this section are proposed in response to comments. Physician determinations and certification requests are typically submitted to the WTC Health Program within 60 days of the completion of the member's examination and/or record review.

Section 88.18 Certification

This section establishes that the WTC Health Program will promptly assess physician determinations submitted by a CCE or NPN-affiliated physician and, if the Program concurs with the determination and decides that a health condition is a WTC-related health condition or a health condition medically associated with a WTC-related health condition, will certify the condition as eligible for coverage under the WTC Health Program. The Administrator has identified the need to amend this section to make necessary clarifications and respond to public comment.

The Administrator proposes to change the number of this existing section from § 88.13 to § 88.18, and to change the title from "WTC Program Administrator's certification of health conditions" to "Certification."

The section would also be amended to include the statutory 60-day deadline for the Program's decision on whether to certify a health condition as medically associated with a WTC-related health condition,[21] as requested by commenters. Specifically, the proposed amendment to paragraph (b) would specify that the Program will notify the WTC Health Program member in writing of the certification decision within 60 calendar days of the date the physician's determination is received.

The language in existing paragraph (c) concerning authorization of treatment pending certification would be removed to a new § 88.20. Language in existing paragraphs (a)(2) and (b)(2) concerning the right to appeal a denial of certification would be consolidated in paragraph (c).

Public comments submitted to the July 2011 IFR docket on this section[22] included concerns about the use of physician panels for the review of health conditions medically associated with WTC-related health conditions, as authorized in the PHS Act and included in paragraph (b). Commenters asserted that the use of the physician panel identified in the rule text is mandatory, that the empaneled physicians should be board certified, and that the Administrator should publicize the qualification criteria for such a panel as well as the names and credentials of empaneled physicians. Finally, commenters asserted that input on panel selection should be sought from the "community," including recommendations from the CCEs, Data Centers, and Steering Committees.

The Administrator interprets the statutory language in section 3312(b)(2)(B) of the PHS Act to require the establishment of procedures governing the use of such a panel. The Administrator finds that in many cases, certification of a medically associated health condition is clearly supported, making panel review unnecessary. The addition of unnecessary administrative layers may delay a decision; therefore, the Administrator declines to make panel review mandatory. Any physician panel members would be chosen for their medical or scientific expertise at the sole discretion of the Administrator.

Commenters also suggested a deadline for certification decisions and recommended that decisions be made within 30 days of the Administrator's receipt of the physicians' determination and request for certification. Although the Administrator declines to set a 30-day deadline for WTC Health Program certification decisions, he is committed to rendering this decision in a timely manner. WTC Health Program members are typically notified of Program decisions within approximately a month of receipt of a physician's determination.

One commenter expressed concern that on-going treatment for a certified condition should not require re-certification each time treatment is necessary. The Administrator agrees. WTC Health Program physicians are not required to request re-certification for on-going treatment of a certified WTC-related health condition.

Finally, one commenter requested that notification regarding a certification decision by the Administrator should be made by certified mail, return receipt requested, and by email where such contact information is available. Although the Administrator generally agrees that notification of any certification decisions made pursuant to this section should be sent by certified mail, he declines to specify in the rule text the mode of transmission, finding the detail potentially detrimental to Program flexibility. He also declines to send notifications by email because receiving more than one notification may be confusing and email notifications do not ensure the protection of private health information.

Section 88.19 Decertification

Similar to the issue of disenrollment, the Administrator has also identified a need for the WTC Health Program to clarify the process for decertification of a WTC-related health condition or health condition medically associated with a WTC-related health condition. Circumstances that would lead to decertification would be limited to those where the condition was certified in error, such as where the WTC Health Program member's 9/11 exposure is later found to be insufficient; the Program decides that the physician erroneously found that the member's 9/11 exposures were substantially likely to be a significant factor in aggravating, contributing to, or causing the health condition; or the Program decides the health condition was erroneously certified as medically associated with a WTC-related health condition. Such concerns may be discovered during routine audit of enrollment decisions. Allowing a health condition to remain certified in error may result in WTC Health Program members receiving treatment for conditions that were not associated with their 9/11-related exposures, leading to inappropriate use of Program services and dollars. The WTC Health Program member would be notified of the decision to decertify the health condition and given an opportunity to appeal the Program's decertification decision.

Section 88.20 Authorization of Treatment

Amendments to the existing section titled "Standard for determining medical necessity" would clarify the WTC Health Program's treatment authorization process. A new paragraph (a) would describe the provision of medically necessary treatment in accordance with applicable Program protocols and policies and procedures.

Paragraph (b) would incorporate the existing standard for determining whether the treatment for a WTC-related health condition or a health condition medically associated with a WTC-related health condition is medically necessary. The Administrator finds it important to clarify that the medical treatment protocols[23] are developed by the Data Centers, with input from the CCEs.

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[20] NIOSH Docket 235, CDC–2011–0009.

[21] *See* PHS Act, sec. 3312(b)(2)(B)(ii).

[22] NIOSH Docket 235, CDC–2011–0009.

The Administrator proposes to amend the original number of this section, § 88.14, to § 88.20, and change the title to "Authorization of treatment." The Administrator further proposes to replace "WTC Program Administrator" with "Administrator of the WTC Health Program."

Public comments submitted to the July 2011 IFR docket on this section[24] included a request that the Administrator create a mechanism by which additional treatment modalities, including alternative therapies not presently part of the existing treatment protocols, would be considered for addition to those existing protocols deemed medically necessary. The Program routinely considers and discusses proposals for new treatment modalities with the CCEs and NPN and reviews available scientific evidence from authoritative bodies to support the inclusion of the proposed treatment modalities.

A new paragraph (c) would incorporate existing language in § 88.13(c) regarding treatment pending certification.

Section 88.21 Appeal of Certification, Decertification, or Treatment Authorization Decision

This section establishes that a WTC Health Program member or the designated representative of such a member may appeal the Program's decision to deny certification of a health condition as WTC-related or medically associated with a WTC-related health condition, decertify a WTC-related health condition or medically associated health condition, or deny authorization of treatment for a certified health condition. Based on Program administrative experience and in response to public comments on the July 2011 IFR,[25] the Administrator has found a need to revise the existing health condition certification and treatment appeals section. Providing more clarity regarding the appeal process will benefit WTC Health Program members and help address concerns raised by commenters asking that the appeal process be more member-friendly. In particular, stakeholders requested that a member be allowed to submit new evidence in support of his or her appeal and interact with the Federal Official reviewing the case.

The Administrator proposes to change the number of this existing section from § 88.15 to § 88.21 and change the section name from "Appeals regarding treatment" to "Appeal of certification, decertification, or treatment authorization decision."

The Administrator proposes to include in paragraph (a)(3) a right of appeal for a WTC Health Program member for whom the Program has decided to decertify a WTC-related health condition or health condition medically associated with a WTC-related health condition, pursuant to proposed language in § 88.19. Members would still be allowed the right to appeal WTC Health Program decisions not to certify a health condition as WTC-related; not to certify a health condition as medically associated with a WTC-related health condition; or to deny treatment authorization for a certified WTC-related health condition or medically associated condition because the treatment is not deemed medically necessary.

Public comments on the July 2011 IFR[26] asked that the Administrator allow the member to appeal a decision made by a CCE or NPN-affiliated physician not to request certification of the member's health condition. Section 3312(b)(1)(A) of the PHS Act requires that a CCE [or NPN-affiliated] physician make a determination regarding the health condition before the WTC Health Program can decide whether to certify the health condition as WTC-related. In accordance with WTC Health Program policies and procedures, a Program member may request a secondary review of the physician's decision not to seek certification of a condition as a WTC-related or medically associated health condition.[27]

Commenters also asked the Administrator to allow the member's physician or CCE medical director to represent the responder or survivor in the appeal, or give the physician the right to appeal the Administrator's certification denial directly. The Administrator declines to allow a CCE or NPN medical director, provider, or staff to represent a member in an appeal because doing so may create a conflict of interest for the medical director, provider, or staff. The Administrator also declines to allow the physician to appeal the certification denial directly; if the physician believes that the Administrator has denied a certification in error, the physician may re-submit the request for certification and provide additional explanation or evidence supporting the physician's determination that the health condition is WTC-related.

The Administrator proposes to amend paragraph (b)(1) to clarify that the appeal process begins when the member or member's designated representative sends a signed letter, either submitted in hard copy or scanned and submitted electronically, to the Administrator requesting the appeal. In response to public comment, the Administrator also proposes to extend the amount of time for filing an appeal from 60 to 90 calendar days from the date of the letter to the member notifying them of the WTC Health Program's adverse decision.

As in the current rule, the appeal request letter must describe the reasons the WTC Health Program's decision is incorrect and should be reversed. For example, the member could argue for reversal on the grounds that factual errors were contained in the scientific or medical information submitted to the Program by the CCE or NPN physician; the Program failed to correctly follow or apply relevant Program policies or procedures; or the Program's decision was unreasonable as applied to the facts of the case. Any basis provided in the appeal request must be sufficiently detailed and supported by information to permit review of the appeal. The Administrator agrees with commenters that the member may have additional relevant information that was not available to the member, the determining physician, or the Program at the time of the decision not to certify the health condition, decertify the condition, or not to authorize treatment. Accordingly, the Administrator now proposes to allow the member or designated representative to submit new information with the appeal request or at a later date, if requested by the Program.

The Administrator proposes to amend portions of the section to clarify the appeal review process and incorporate procedures the WTC Health Program has outlined elsewhere.[28] As requested by commenters, the Administrator proposes new paragraph (b)(3) to codify the WTC Health Program's current process allowing the Program member or the member's designated representative the opportunity to make a 15-minute oral statement by telephone.[29] A transcript of the oral statement is included in the record and provided to the Program member and/or the member's designated representative. The Administrator finds that more formal hearings would be administratively burdensome, divert Program resources away from patient care, and be of little benefit to the member.

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[23] *See Policy and Procedure Manual for the WTC Health Program*, Jan. 1, 2015, Chapter 4: Medical Benefits, Section 4: Covered Medical Services, Part B: Medically Necessary Treatment, *http://www.cdc.gov/wtc/ppm.html#4d.* Program communications sometimes also refer to medical treatment protocols as "medical guidelines."

[24] NIOSH Docket 235, CDC–2011–0009.

[25] NIOSH Docket 235, CDC–2011–0009.

[26] NIOSH Docket 235, CDC–2011–0009.

[27] *See Policy and Procedure Manual for the WTC Health Program*, Jan. 1, 2015, Chapter 3: Certification of Health Conditions, Section 5: CCE/NPN Physician Determination and Request for Certification of Health Conditions, Part B: Secondary Review of Negative Physician Determination, *http://www.cdc.gov/wtc/ppm.html#3e.*

Finally, the Administrator proposes to amend paragraph (c) to clarify that after receipt of the appeal request, the Administrator assigns an independent Federal Official to review the case and the WTC Health Program's decision not to certify the health condition or medically associated condition, to decertify, or not to authorize treatment. The Federal Official decides whether to recommend granting the appeal by considering whether the WTC Health Program substantially complied with all relevant Program policies and procedures; whether the information supporting the Program's decision was factually accurate; and whether the Program's decision was reasonable as applied to the facts of the case.

Proposed paragraph (c)(1) would clarify that the Federal Official will review the case record, including any oral statement made by the WTC Health Program member or the member's designated representative, as well as any additional relevant new information submitted with the appeal request or provided at the request of the WTC Health Program. As established in paragraph (b)(2) of the current rule, proposed paragraph (c)(2) would state that the Federal Official may consult one or more qualified experts; amendments to this paragraph would permit any experts consulted to review the WTC Health Program's adverse decision and the Program member's records as well as any new information provided by the member during the appeal. As described in proposed paragraph (c)(3), the Federal Official will submit his or her recommendation to the Administrator. The recommendation would include the Federal Official's recommendation and findings regarding the disposition of the appeal and any relevant supporting materials, including the transcript of any oral statement and the findings of any experts. One commenter asserted that some of the experts must be unaffiliated with the Federal government to prevent bias and that community input should be obtained for the selection of experts, including from the WTC Health Program survivor and responder steering committees and CCEs. The Administrator declines to adopt this suggestion and notes that relevant expertise is likely to be related to exposure assessments and medical findings. Further, the Federal Official may consult one or more expert reviewers when deemed necessary; the use of expert reviewers may not always be beneficial and could result in administrative burden and delay.

The Administrator proposes to further revise the section by adding paragraph (d), which would recharacterize the outcome of the Federal Official's review of the appeal as a recommendation to be provided to the Administrator. In the final step of the appeal process, the Administrator would review the Federal Official's recommendation and supporting materials and make a final decision regarding the certification, decertification, or treatment authorization decision being appealed. The Administrator would notify the member and/or the member's designated representative of the Federal Official's findings and recommendation, the Administrator's final decision, and provide an explanation of the decision and any administrative actions taken by the WTC Health Program in response to the final decision. The Administrator declines to adopt a deadline for notification of a final appeal decision, as requested by public comment on the July 2011 IFR.[30] Given the potentially complex nature of appeals decisions, the Administrator is concerned that limiting the amount of time available to the Federal Official and/or the Administrator to review the Program member's file (including any new information submitted) could result in undue burden and prevent a thorough review of the appeal.

Finally, for administrative clarity, the Administrator proposes striking existing paragraph (c), which allows the Administrator to reopen final decisions, and moving the text from this section to a new section § 88.25.

Section 88.22 Reimbursement for Medical Treatment and Services

A new § 88.22 would comprise language formerly found in § 88.16. This section establishes how the WTC Health Program will reimburse or pay for the cost of monitoring, initial health evaluations, medical treatment, and outpatient prescription pharmaceuticals.

The Administrator proposes to change the number of this existing section from § 88.16 to § 88.22, and to move provisions regarding travel expenses, unchanged, out of this section and into § 88.2, General provisions (*see* above). The existing language would be rearranged slightly. Existing paragraph (c)(1) would be redesignated as paragraph (a) to clarify that each reimbursement or payment claim is reviewed by the WTC Health Program and that claims that cannot be validated will be further assessed by the Administrator. Paragraph (b)(1) would consolidate existing language about reimbursement for costs associated with initial health evaluations, medical monitoring, and medically necessary treatment, and also correct the reference to regulations implementing the Federal Employees Compensation Act (FECA), 20 CFR part 10. New text in paragraph (b)(1)(ii) would clarify that treatment for which rates have not been established under either FECA or Medicare fee for service rate schedules, such as dental services, is reimbursed at rates set by the Administrator.[31] Language would be added to paragraph (b)(2) to clarify that the Administrator may withhold reimbursement if the treatment is inconsistent with WTC Health Program protocols, pursuant to language in section 3312(c)(3) of the PHS Act.

Paragraph (c) would include language from existing paragraph (a)(2). The term "pharmaceutical providers" would be replaced with "pharmaceutical benefit management services."

Section 88.23 Appeal of Reimbursement Denial

The Administrator has determined that the right of a CCE or NPN medical director or affiliated provider to appeal a WTC Health Program decision not to authorize reimbursement or payment for treatment should be included in Part 88 for clarity and completeness. This appeal right is established in section 3312(b)(3)(B) of the PHS Act, which calls on the Administrator to establish a process for appeal of a determination under section 3312(c)(3). Section 3312(c)(3) authorizes the WTC Health Program to withhold reimbursement or payment for treatment provided when it determines the treatment is not medically necessary or is not in accordance with medical treatment protocols.

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[28] *See* WTC Health Program: Appeals Process, *Overview of the Appeal Process For Denial of Health Condition Certification, http://www.cdc.gov/wtc/appeals_condition.html.* The 15-minute oral statement allows the member to present his or her case to the Federal Official assigned to review the case; however, the member is not permitted to present witnesses and the Federal Official does not issue a ruling at the conclusion of the oral statement.

[29] *See id.*

[30] NIOSH Docket 235, CDC–2011–0009.

[31] Rates for dental services are available in the *Policy and Procedure Manual for the WTC Health Program,* Jan. 1, 2015, Chapter 4: Medical Benefits, Section 28: Medically Necessary Dental Care, *http://www.cdc.gov/wtc/ppm.html.*

Accordingly, the Administrator proposes to establish an appeal process in § 88.23 to allow the CCE or NPN medical director or affiliated provider to appeal such decisions where all contractual or procedural remedies have been exhausted. Appeals of WTC Health Program decisions to not authorize reimbursement or payment for treatment would be made in accordance with Program policies and procedures published on the Program Web site.

Section 88.24 Coordination of Benefits and Recoupment

The Administrator proposes to add a new section to address the matter of coordination of benefits, including recoupment from workers' compensation settlements. Pursuant to section 3331 of the PHS Act, this section would explain that the WTC Health Program attempts to recover the costs associated with treatment, including pharmacy benefits, for a member's certified WTC-related health condition or medically associated health condition in certain situations. As directed by the Act, the WTC Health Program coordinates benefits with any workers' compensation insurance available[32] for members' work-related[33] conditions, and with any public or private health insurance available for members' non-work-related conditions.

Proposed paragraph (a) would describe circumstances in which the WTC Health Program member is eligible for workers' compensation or another illness or injury benefit plan to which New York City is obligated to pay.

Proposed paragraph (b) would describe circumstances in which the WTC Health Program member has filed a workers' compensation claim but the claim is still pending acceptance by the workers' compensation board.

Proposed paragraph (c) would describe circumstances in which the WTC Health Program member has filed a workers' compensation claim but a final decision is issued denying coverage for medical treatment of the condition.

Proposed paragraph (d) would describe circumstances in which the WTC Health Program member has filed a successful claim for a certified WTC-related health condition or medically associated health condition with a workers' compensation plan to which New York City is not obligated to pay. In this case, the WTC Health Program recoups costs for treatment from the workers' compensation insurer. As described in proposed paragraph (d)(1), if the WTC Health Program member settles the workers' compensation claim by entering into a settlement agreement that releases the employer or insurance carrier from paying for future medical care, the agreement must protect the WTC Health Program's interests regarding future medical expenses that might otherwise have been paid for by the workers' compensation insurance.[34] If the WTC Health Program member has accepted a lump sum or other payment award for future medical care, the WTC Health Program may require the member to reimburse the Program for treatment services provided after receipt of the award. Proposed paragraph (d)(2) would also clarify that the WTC Health Program pays providers for treatment in accordance with the rates recognized under § 88.22(b) of this part, but recoups at the worker's compensation rate, if lower than the WTC Health Program rates.

Proposed paragraph (e) would describe circumstances in which the WTC Health Program member's certified health condition is not work-related and the member's public or private health insurance plan is the primary payer. In such cases, the WTC Health Program pays costs not reimbursed by the public or private health insurance plan due to the application of deductibles, co-payments, co-insurance, other cost sharing arrangements, or payment caps up to and in accordance with the rates described in § 88.22(b) of this part.[35]

Finally, proposed paragraph (f) would describe how the WTC Health Program handles situations that are not specifically covered by proposed paragraphs (a)–(e) described above and refers interested parties to the Program policies and procedures[36] for further guidance.

Section 88.25 Reopening of WTC Health Program Final Decisions

As discussed above, the Administrator proposes the creation of a new section to clarify the Administrator's authority to reopen any final decisions made by the WTC Health Program, including those concerning enrollment, health condition certification, and appeals. At any time, and without regard to whether new evidence or information is provided or obtained, the Administrator may reopen a final decision and may affirm, vacate, or modify such decision, or take any other action he or she deems appropriate. Such reopenings may be necessary to address administrative errors or to incorporate or address changes in Program eligibility criteria, regulations, or policies and procedures. This authority is currently described in the two existing appeals sections, at §§ 88.11(c) and 88.15(c); for clarity and to aid administrative decision-making, the Administrator intends to consolidate the authority into one section.

V. Regulatory Assessment Requirements

A. Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, and public health and safety effects, distributive impacts, and equity). Executive Order 13563 emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility.

This proposed rule has been determined not to be a "significant regulatory action" under section 3(f) of Executive Order 12866. With this action, the Administrator is proposing amendments to certain sections in 42 CFR part 88. Non-substantive amendments would include a reorganization of provisions from the existing § 88.10 into new §§ 88.11 and 88.12 and the addition of a new § 88.15, List of WTC-Related Health Conditions. Reorganization of this part would necessitate the renumbering of existing Part 88 sections, which would be done throughout the regulatory text. The Administrator would also clarify throughout Part 88 that deadlines are calculated in terms of calendar days. An amendment to the existing section regarding the physician's determination of WTC-related health conditions would clarify that the determination must be predicated upon the statutory requirements for a WTC-related health condition. Various other minor clarifications of WTC Health Program practice would be made throughout Part 88.

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[32] To the extent that payment for treatment of the member's work-related condition has been made, or can reasonably be expected to be made, under any other work-related injury or illness benefit plan of the member's employer, the WTC Health Program will also attempt to recover the costs associated with treatment, including pharmacy benefits, for the member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition. *See* PHS Act, sec. 3331(b)(1). For purposes of this regulation, "workers' compensation law or plan" or "workers' compensation insurance" includes any other work-related injury or illness benefit plan of the WTC Health Program member's employer.

[33] The term "work-related" is defined in sec. 3331(e) of the PHS Act to mean: "(1) the condition is diagnosed in an enrolled WTC responder, or in an individual who qualifies as a certified-eligible WTC survivor on the basis of being a rescue, recovery, or cleanup worker; or (2) with respect to the condition the individual has filed and had [*sic*] established a claim under a workers' compensation law or plan of the United States or a State, or other work-related injury or illness benefit plan of the employer of such individual."

[34] *Policy and Procedures for Recoupment: Lump-Sum Workers' Compensation Settlements,* addressing the adequacy of settlement agreements to protect the WTC Health Program's interests, is found on the Program's Policies and Procedures Web page, at *http://www.cdc.gov/wtc/policies.html.*

[35] PHS Act, sec. 3331(c)(1).

[36] Policies and procedures describing recoupment and coordination of benefits are found on the WTC Health Program's Web site at *http://www.cdc.gov/wtc/policies.html.*

New, substantive regulatory text would be added to Part 88 to define the term "WTC Health Program member," codify an existing statutory appeal right for CCEs and NPN-affiliated providers, and codify existing WTC Health Program policies regarding the disenrollment of WTC Health Program members, decertification of certified WTC-related health conditions, and coordination of benefits.

Amendments to the existing provision regarding the addition of health conditions to the List of WTC-Related Health Conditions would include the following: A valid petition must include the petitioner's signature; the statutory deadline for a response to a petition is extended from 60 to 90 calendar days and may be tolled while the Administrator seeks clarification from the interested party regarding the submission, if necessary; and the Administrator would not consider a submission to be a valid petition if it does not provide a new medical basis for the addition of the health condition and is received after the publication of a response in the **Federal Register** to a petition requesting the addition of the same health condition.

Lastly, amendments to the existing certification and treatment authorization appeals section would codify existing WTC Health Program policy and also allow for an appeal of a Program decision to decertify a WTC-related health condition.

This proposed rule does not result in substantial costs to the WTC Health Program, Program members, or stakeholders, nor does it raise any novel legal or policy issues. The Administrator finds that amendments to § 88.14 and § 88.21 (enrollment and medical appeals) and § 88.16 (addition of health conditions) will result in necessary changes to several existing WTC Health Program policies; the proposed novel regulatory provisions in § 88.13 (disenrollment), § 88.19 (decertification), and § 88.23 (reimbursement appeals) will require the revision of existing policies or development of new policies.

The Administrator estimates that amending the existing *Policy and Procedures for Handling Submissions and Petitions to Add a Health Condition to the List of WTC-Related Health Conditions* and the Web page containing frequently asked questions regarding appeals, and developing new disenrollment, decertification, and reimbursement appeal policies will require approximately 568 hours of staff time. Accordingly, this rulemaking is expected to cost the WTC Health Program approximately $42,742.

This rule does not interfere with State, local, or Tribal governments in the exercise of their governmental functions.

B. Regulatory Flexibility Act

The Regulatory Flexibility Act (RFA), 5 U.S.C. 601 *et seq.,* requires each agency to consider the potential impact of its regulations on small entities including small businesses, small governmental units, and small not-for-profit organizations. The Administrator certifies that this proposed rule has "no significant economic impact upon a substantial number of small entities" within the meaning of the RFA.

C. Paperwork Reduction Act

The Paperwork Reduction Act, 44 U.S.C. 3501 *et seq.,* requires an agency to invite public comment on, and to obtain OMB approval of, any regulation that requires 10 or more people to report information to the agency or to keep certain records. Data collection and recordkeeping requirements for the WTC Health Program are approved by OMB under "World Trade Center Health Program Enrollment, Appeals & Reimbursement" (OMB Control No. 0920–0891, exp. September 30, 2018). HHS has determined that non-substantive changes may be needed to the information collection request already approved by OMB and that these revisions would not result in any change in respondent burden.

D. Small Business Regulatory Enforcement Fairness Act

As required by Congress under the Small Business Regulatory Enforcement Fairness Act of 1996, 5 U.S.C. 801 *et seq.,* HHS will report the promulgation of this rule to Congress prior to its effective date.

E. Unfunded Mandates Reform Act of 1995

Title II of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1531 *et seq.,* directs agencies to assess the effects of Federal regulatory actions on State, local, and Tribal governments, and the private sector "other than to the extent that such regulations incorporate requirements specifically set forth in law." For purposes of the Unfunded Mandates Reform Act, this proposed rule does not include any Federal mandate that may result in increased annual expenditures in excess of $100 million in 1995 dollars by State, local, or Tribal governments in the aggregate, or by the private sector.

F. Executive Order 12988 (Civil Justice)

This proposed rule has been drafted and reviewed in accordance with Executive Order 12988, "Civil Justice Reform," and will not unduly burden the Federal court system. This rule has been reviewed carefully to eliminate drafting errors and ambiguities.

G. Executive Order 13132 (Federalism)

The Administrator has reviewed this proposed rule in accordance with Executive Order 13132 regarding Federalism, and has determined that it does not have "Federalism implications." The rule does not "have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government."

H. Executive Order 13045 (Protection of Children From Environmental Health Risks and Safety Risks)

In accordance with Executive Order 13045, the Administrator has evaluated the environmental health and safety effects of this proposed rule on children. The Administrator has determined that the rule would have no environmental health and safety effect on children.

I. Executive Order 13211 (Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use)

In accordance with Executive Order 13211, the Administrator has evaluated the effects of this proposed rule on energy supply, distribution or use, and has determined that the rule will not have a significant adverse effect.

J. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive Departments and Agencies are required to use plain language in documents that explain to the public how to comply with a requirement the Federal government administers or enforces. The Administrator has attempted to use plain language in promulgating the proposed rule consistent with the Federal Plain Writing Act guidelines and requests public comment on this effort.

List of Subjects in 42 CFR Part 88

Aerodigestive disorders, Appeal procedures, Health care, Mental health conditions, Musculoskeletal disorders, Respiratory and pulmonary diseases.

Proposed Rule

For the reasons discussed in the preamble, the Administrator proposes to amend 42 CFR part 88 as follows:

PART 88—WORLD TRADE CENTER HEALTH PROGRAM

■ 1. The authority citation for Part 88 is amended to read as follows:

Authority: 42 U.S.C. 300mm to 300mm-61, Pub. L. 111–347, 124 Stat. 3623, as amended by Pub. L. 114–113, 129 Stat. 2242.

■ 2. In § 88.1, revise the definitions "Act", "Certification", "Certified-eligible survivor", "Clinical Center of Excellence", "List of World Trade Center (WTC)-related health conditions", "Medically necessary treatment", "Nationwide provider network", "World Trade Center (WTC) Health Program", "World Trade Center (WTC) Program Administrator", "World Trade Center (WTC)-related health condition", and "World Trade Center (WTC)-related musculoskeletal disorder", and add "World Trade Center (WTC) Health Program member" and "World Trade Center (WTC)-related acute traumatic injury" to read as follows:

§ 88.1 Definitions.

Act means Title XXXIII of the Public Health Service Act, as amended, 42 U.S.C. 300mm through 300mm–61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111–347, as amended by Pub. L. 114–113), which created the World Trade Center (WTC) Health Program.

* * * * *

Certification means WTC Health Program review of a health condition in a particular WTC Health Program member for the purpose of identification and approval of a WTC-related health condition, as defined in this section and included on the List of WTC-Related Health Conditions in 42 CFR 88.15, or a health condition medically associated with a WTC-related health condition.

Certified-eligible survivor means (1) an individual who has been identified as eligible for medical monitoring and treatment as of January 2, 2011; or (2) a screening-eligible survivor who is eligible for follow-up monitoring and treatment pursuant to § 88.12(b).

Clinical Center of Excellence (CCE) means a center or centers under contract with the WTC Health Program. A CCE:

(1) Uses an integrated, centralized health care provider approach to create a comprehensive suite of health services that are accessible to enrolled WTC responders, screening-eligible survivors, or certified-eligible survivors;

(2) Has experience in caring for WTC responders and screening-eligible survivors, or includes health care providers who have received WTC Health Program training;

(3) Employs health care provider staff with expertise that includes, at a minimum, occupational medicine, environmental medicine, trauma-related psychiatry and psychology, and social services counseling; and

(4) Meets such other requirements as specified by the Administrator of the WTC Health Program.

* * * * *

List of WTC-Related Health Conditions means those conditions eligible for coverage in the WTC Health Program as identified in § 88.15 of this part.

* * * * *

Medically necessary treatment means the provision of services to a WTC Health Program member by physicians and other health care providers, including diagnostic and laboratory tests, prescription drugs, inpatient and outpatient hospital services, and other care that is appropriate, to manage, ameliorate, or cure a WTC-related health condition or a health condition medically associated with a WTC-related health condition, and which conforms to medical treatment protocols developed by the Data Centers, with input from the Clinical Centers of Excellence, and approved by the Administrator of the WTC Health Program.

* * * * *

Nationwide Provider Network (NPN) means a network of providers throughout the United States under contract with the WTC Health Program to provide an initial health evaluation, monitoring, and treatment to enrolled WTC responders, screening-eligible survivors, or certified-eligible survivors who live outside the New York metropolitan area.

* * * * *

World Trade Center (WTC) Health Program means the program established by Title XXXIII of the Public Health Service Act as amended, 42 U.S.C. 300mm to 300mm–61 (codifying Title I of the James Zadroga 9/11 Health and Compensation Act of 2010, Pub. L. 111–347, as amended by Pub. L. 114–113) to provide medical monitoring and treatment benefits for eligible responders to the September 11, 2001, terrorist attacks and initial health evaluation, monitoring, and treatment benefits for residents and other building occupants and area workers in New York City who were directly impacted and adversely affected by such attacks.

World Trade Center (WTC) Health Program member means any responder, screening-eligible survivor, or certified-eligible survivor enrolled in the WTC Health Program.

World Trade Center (WTC) Program Administrator (Administrator of the WTC Health Program, or Administrator) means, for the purposes of this part, the Director of the National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services, or his or her designee.

World Trade Center (WTC)-related acute traumatic injury means the health condition eligible for coverage in the WTC Health Program as described in § 88.15(e)(1) of this part.

World Trade Center (WTC)-related health condition means an illness or health condition for which exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, based on an examination by a medical professional with expertise in treating or diagnosing the health conditions in the List of WTC-Related Health Conditions, is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, including a mental health condition. Only those conditions on the List of WTC-Related Health Conditions codified in 42 CFR 88.15 may be considered WTC-related health conditions.

World Trade Center (WTC)-related musculoskeletal disorder means the health condition eligible for coverage in the WTC Health Program as described in § 88.15(c)(1) of this part.

* * * * *

■ 3. Revise § 88.2 to read as follows:

§ 88.2 General provisions.

(a) *Designated representative.* (1) An applicant or WTC Health Program member may appoint one individual to represent his or her interests under the WTC Health Program. The appointment must be made in writing and consistent with all relevant Federal laws and regulations in order for the designated representative to receive personal health information.

(2) There may be only one designated representative at any time. After one designated representative has been properly appointed, the WTC Health Program will not recognize another individual as the designated representative until the appointment of the previously designated representative is withdrawn in a signed writing.

(3) A properly appointed designated representative who is recognized by the WTC Health Program may make a request or give direction to the WTC Health Program regarding the eligibility, certification, or any other administrative issue pertaining to the applicant or WTC Health Program member under the WTC Health Program, including appeals. Any notice requirement contained in this part or in the Act is fully satisfied if sent to the designated representative.

(4) An applicant or WTC Health Program member may authorize any individual to represent him or her in regard to the WTC Health Program, unless that individual's service as a representative would violate any applicable provision of law (such as 18 U.S.C. 205 or 18 U.S.C. 208) or is otherwise prohibited by WTC Health Program policies and procedures or contract provisions.

(5) A Federal employee may act as a representative only on behalf of the individuals specified in, and in the manner permitted by, 18 U.S.C. 203 and 18 U.S.C. 205.

(6) If a screening-eligible or certified-eligible survivor is a minor, a parent or guardian may act on his or her behalf.

(b) *Transportation and travel expenses.* The Administrator of the WTC Health Program may provide for necessary and reasonable transportation and expenses incident to the securing of medically necessary treatment through the NPN, involving travel of more than 250 miles.

■ 4. Amend § 88.4 to revise the section heading to read as follows:

§ 88.4 Eligibility criteria—WTC responders.

■ 5. Amend § 88.5 to revise the section heading to read as follows:

§ 88.5 Application process—WTC responders.

■ 6. Revise § 88.6 to read as follows:

§ 88.6 Enrollment decision—WTC responders.

(a) The WTC Health Program will prioritize applications in the order in which they are received.

(b) The WTC Health Program will decide if the applicant meets the eligibility criteria provided in § 88.4 and notify the applicant in writing (or by email if an email address is provided by the applicant) of any deficiencies in the application or the supporting documentation.

(c) *Denial of enrollment.* (1) The WTC Health Program will deny enrollment if the applicant fails to meet the applicable eligibility requirements.

(2) The WTC Health Program may deny enrollment of a responder who is otherwise eligible and qualified if the Act's numerical limitations for newly enrolled responders have been met.

(i) No more than 25,000 WTC responders, other than those enrolled pursuant to §§ 88.3 and 88.4(a)(1)(ii), may be enrolled at any time. The Administrator of the WTC Health Program may decide, based on the best available evidence, that sufficient funds are available under the WTC Health Program Fund to provide treatment and monitoring only for individuals who are already enrolled as WTC responders at that time.

(ii) [Reserved]

(3) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be enrolled or be determined to be eligible for the WTC Health Program.

(d) *Notification of enrollment decision.* (1) Applicants who meet the current eligibility criteria for WTC responders in § 88.4 and are qualified will be notified in writing by the WTC Health Program of the enrollment decision within 60 calendar days of the date of receipt of the application.

(2) If the WTC Health Program decides that an applicant is denied enrollment, the applicant will be notified in writing and provided an explanation, as appropriate, for the decision to deny enrollment. The notification will inform the applicant of the right to appeal the initial denial of eligibility and provide instructions on how to file an appeal.

■ 7. Amend § 88.8 to revise the section heading to read as follows:

§ 88.8 Eligibility criteria—WTC survivors.

■ 8. Amend § 88.9 to revise the section heading to read as follows:

§ 88.9 Application process—WTC survivors.

■ 9. Revise §§ 88.10 through 88.18 to read as follows:

§ 88.10 Enrollment decision—screening-eligible survivors.

(a) The WTC Health Program will decide if the applicant meets the screening-eligibility criteria pursuant to § 88.8(a) and notify the applicant of the decision in writing within 60 calendar days of the date of receipt of the application. The applicant will be notified of any deficiencies in the application or the supporting documentation. The 60-day time period will not include any days during which the applicant is correcting deficiencies in the application or supporting documentation.

(b) If the WTC Health Program decides that an applicant is denied enrollment, the applicant will be notified in writing and provided an explanation for the decision to deny enrollment. The notification will inform the applicant of the right to appeal the enrollment denial and provide instructions on how to file an appeal.

(1) The WTC Health Program may deny screening-eligible survivor status if the applicant is ineligible under the criteria specified in § 88.8(a).

(2) The WTC Health Program may deny screening-eligible survivor status if the numerical limitation on certified-eligible survivors in § 88.12(b)(3)(i) has been met.

(3) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be a screening-eligible survivor in the WTC Health Program.

§ 88.11 Initial health evaluation for screening-eligible survivors.

(a) A CCE or NPN will provide the screening-eligible survivor an initial health evaluation to determine if the individual has a WTC-related health condition.

(b) The WTC Health Program will provide only one initial health evaluation per screening-eligible survivor. The individual may request additional health evaluations at his or her own expense.

(c) If the physician determines that the screening-eligible survivor has a WTC-related health condition, the physician will promptly transmit to the WTC Health Program his or her determination, consistent with the requirements of § 88.17(a).

§ 88.12 Enrollment decision—certified-eligible survivors.

(a) The WTC Health Program will prioritize certification requests in the order in which they are received.

(b) The WTC Health Program will review the physician's determination, render a decision regarding certification of the individual's WTC-related health condition, and notify the individual of the decision and the reason for the decision in writing, pursuant to §§ 88.17 and 88.18.

(1) If the individual is a screening-eligible survivor and the individual's condition is certified as a WTC-related health condition, the individual will automatically receive the status of a certified-eligible survivor.

(2) If a screening-eligible survivor's condition is not certified as a WTC-related health condition pursuant to §§ 88.17 and 88.18, the WTC Health Program will deny certified-eligible status. The screening-eligible survivor may appeal the decision to deny certification, as provided under § 88.21.

(3) The WTC Health Program may deny certified-eligible survivor status of an otherwise eligible and qualified screening-eligible survivor if the Act's numerical limitations for certified-eligible survivors have been met.

(i) No more than 25,000 individuals, other than those described in § 88.7, may be determined to be certified-eligible survivors at any time. The Administrator of the WTC Health Program may decide, based on the best available evidence, that sufficient funds are available under the WTC Health Program Fund to provide treatment and monitoring only for individuals who have already been certified as certified-eligible survivors at that time.

(ii) [Reserved]

(4) No individual who is determined to be a positive match to the terrorist watch list maintained by the Federal government may qualify to be a certified-eligible survivor in the WTC Health Program.

§ 88.13 Disenrollment.

(a) The disenrollment of a WTC Health Program member may be initiated by the WTC Health Program in the following circumstances:

(1) The WTC Health Program mistakenly enrolled an individual under § 88.4 (WTC responders) or § 88.8 (screening-eligible survivors) who did not provide sufficient proof of eligibility consistent with the required eligibility criteria; or

(2) The WTC Health Program member's enrollment was based on incorrect or fraudulent information.

(b) The disenrollment of a WTC Health Program member may be initiated by the enrollee for any reason.

(c) A disenrolled WTC Health Program member will be notified in writing by the WTC Health Program of a disenrollment decision, provided an explanation, as appropriate, for the decision, and provided information on how to appeal the decision. A disenrolled WTC Health Program member disenrolled pursuant to paragraph (a) may appeal the disenrollment decision in accordance with § 88.14.

(d) A disenrolled WTC Health Program member who has been disenrolled in accordance with paragraphs (a) or (b) of this section may seek to re-enroll in the WTC Health Program using the application and enrollment procedures, provided that the application is supported by new information.

§ 88.14 Appeal of enrollment or disenrollment decision.

(a) An applicant denied WTC Health Program enrollment, a disenrolled WTC Health Program member, or the applicant's or member's designated representative (appointed pursuant to § 88.2(a)) may appeal the enrollment denial or disenrollment decision.

(b) *Appeal request.* (1) A letter requesting an appeal must be postmarked within 90 calendar days of the date of the letter from the Administrator notifying the denied applicant or disenrolled WTC Health Program member of the adverse decision. Electronic versions of a signed letter will be accepted if transmitted within 90 days of the date of the Administrator's notification letter.

(2) A valid request for an appeal must:

(i) Be made in writing and signed;

(ii) Identify the denied applicant or disenrolled WTC Health Program member and designated representative (if applicable);

(iii) Describe the decision being appealed and state the reasons why the denied applicant, disenrolled WTC Health Program member, or designated representative believes the enrollment denial or disenrollment was incorrect and should be reversed. The appeal request may include relevant new information not previously considered by the WTC Health Program; and

(iv) Be sent to the WTC Health Program at the address specified in the notice of denial or disenrollment.

(3) Where the denial or disenrollment is based on information from the terrorist watch list, the appeal will be forwarded to the appropriate Federal agency.

(c) *Appeal process.* Upon receipt of a valid appeal, the Administrator will appoint a Federal Official independent of the WTC Health Program to review the case. The Federal Official will review all available records relevant to the WTC Health Program's decision not to enroll the applicant or to disenroll the WTC Health Program member, and assess whether the appeal should be granted. In conducting the review, the Federal Official's consideration will include the following: whether the WTC Health Program substantially complied with all relevant WTC Health Program policies and procedures; whether the information supporting the WTC Health Program's decision was factually accurate; and whether the WTC Health Program's decision was reasonable as applied to the facts of the case.

(1) The Federal Official may consider additional relevant new information submitted by the denied applicant, disenrolled WTC Health Program member, or designated representative.

(2) The Federal Official will provide his or her recommendation regarding the disposition of the appeal, including his or her findings and any supporting materials, to the Administrator.

(d) *Final decision and notification.* The Administrator will review the Federal Official's recommendation and any relevant information and make a final decision on the appeal. The Administrator will notify the denied applicant or disenrolled WTC Health Program member and/or designated representative of the following in writing:

(1) The recommendation and findings made by the Federal Official as a result of the review;

(2) The Administrator's final decision on the appeal;

(3) An explanation of the reason(s) for the Administrator's final decision on the appeal; and

(4) Any administrative actions taken by the WTC Health Program in response to the Administrator's final decision.

§ 88.15 List of WTC-Related Health Conditions.

WTC-related health conditions include the following disorders and conditions:

(a) *Aerodigestive disorders:*

(1) Interstitial lung diseases.

(2) Chronic respiratory disorder—fumes/vapors.

(3) Asthma.

(4) Reactive airways dysfunction syndrome (RADS).

(5) WTC-exacerbated and new-onset chronic obstructive pulmonary disease (COPD).

(6) Chronic cough syndrome.

(7) Upper airway hyperreactivity.

(8) Chronic rhinosinusitis.

(9) Chronic nasopharyngitis.

(10) Chronic laryngitis.

(11) Gastroesophageal reflux disorder (GERD).

(12) Sleep apnea exacerbated by or related to a condition described in preceding paragraphs (1)–(11).

(b) *Mental health conditions.*

(1) Posttraumatic stress disorder (PTSD).

(2) Major depressive disorder.

(3) Panic disorder.

(4) Generalized anxiety disorder.

(5) Anxiety disorder (not otherwise specified).

(6) Depression (not otherwise specified).

(7) Acute stress disorder.

(8) Dysthymic disorder.

(9) Adjustment disorder.

(10) Substance abuse.

(c) *Musculoskeletal disorders:*

(1) WTC-related musculoskeletal disorder is a chronic or recurrent disorder of the musculoskeletal system caused by heavy lifting or repetitive strain on the joints or musculoskeletal system occurring during rescue or recovery efforts in the New York City disaster area in the aftermath of the September 11, 2001, terrorist attacks. For a WTC responder who received any treatment for a WTC-related musculoskeletal disorder on or before September 11, 2003, such health condition includes:

(i) Low back pain.

(ii) Carpal tunnel syndrome (CTS).

(iii) Other musculoskeletal disorders.

(2) [Reserved].

(d) *Cancers:*

(1) Malignant neoplasms of the lip; tongue; salivary gland; floor of mouth; gum and other mouth; tonsil; oropharynx; hypopharynx; and other oral cavity and pharynx.

(2) Malignant neoplasm of the nasopharynx.

(3) Malignant neoplasms of the nose; nasal cavity; middle ear; and accessory sinuses.

(4) Malignant neoplasm of the larynx.

(5) Malignant neoplasm of the esophagus.

(6) Malignant neoplasm of the stomach.

(7) Malignant neoplasm of the colon and rectum.

(8) Malignant neoplasm of the liver and intrahepatic bile duct.

(9) Malignant neoplasms of the retroperitoneum and peritoneum; omentum; and mesentery.

(10) Malignant neoplasms of the trachea; bronchus and lung; heart, mediastinum and pleura; and other ill-defined sites in the respiratory system and intrathoracic organs.

(11) Mesothelioma.

(12) Malignant neoplasms of the peripheral nerves and autonomic nervous system; and other connective and soft tissue.

(13) Malignant neoplasms of the skin (melanoma and non-melanoma), including scrotal cancer.

(14) Malignant neoplasm of the female breast.

(15) Malignant neoplasm of the ovary.

(16) Malignant neoplasm of the prostate.

(17) Malignant neoplasm of the urinary bladder.

(18) Malignant neoplasm of the kidney.

(19) Malignant neoplasms of the renal pelvis, ureter, and other urinary organs.

(20) Malignant neoplasms of the eye and orbit.

(21) Malignant neoplasm of the thyroid.

(22) Malignant neoplasms of the blood and lymphoid tissues (including, but not limited to, lymphoma, leukemia, and myeloma).

(23) Childhood cancers: any type of cancer diagnosed in a person less than 20 years of age.

(24) Rare cancers: any type of cancer[37] that occurs in less than 15 cases per 100,000 persons per year in the United States.

(e) *Acute traumatic injuries:*

(1) WTC-related acute traumatic injury is physical damage to the body caused by and occurring immediately after a one-time exposure to energy, such as heat, electricity, or impact from a crash or fall, resulting from a specific event or incident. For a WTC responder or screening-eligible or certified-eligible survivors who received any medical treatment for a WTC-related acute traumatic injury on or before September 11, 2003, such health condition includes:

(i) Eye injury.

(ii) Burn.

(iii) Head trauma.

(iv) Fracture.

(v) Tendon tear.

(vi) Complex sprain.

(vii) Other similar acute traumatic injuries.

(2) [Reserved]

§ 88.16 Addition of health conditions to the List of WTC-Related Health Conditions.

(a) Any interested party may submit a request to the Administrator of the WTC Health Program to add a condition to the List of WTC-Related Health Conditions in § 88.15. The Administrator will evaluate the submission to decide whether it is a valid petition.

(1) Each valid petition must include the following:

(i) An explicit statement of an intent to petition the Administrator to add a health condition to the List of WTC-Related Health Conditions;

(ii) Name, contact information, and signature of the interested party petitioning for the addition;

(iii) Name and/or description of the condition(s) to be added;

(iv) Reasons for adding the condition(s), including the medical basis for the association between the September 11, 2001, terrorist attacks and the condition(s) to be added.

(2) Not later than 90 calendar days after the receipt of a valid petition, the Administrator will take one of the following actions:

(i) Request a recommendation of the WTC Health Program Scientific/Technical Advisory Committee;

(ii) Publish in the **Federal Register** a proposed rule to add such health condition;

(iii) Publish in the **Federal Register** the Administrator's decision not to publish a proposed rule and the basis for that decision; or

(iv) Publish in the **Federal Register** a decision that insufficient evidence exists to take action under paragraph (a)(2)(i) through (iii) of this section.

(3) The 90-day time period will not include any days during which the Administrator is consulting with the interested party to clarify the submission.

(4) The Administrator may consider more than one petition simultaneously when the petitions propose the addition of the same health condition. Scientific/Technical Advisory Committee recommendations and **Federal Register** notices initiated by the Administrator pursuant to paragraph (a)(2) of this section may respond to more than one petition.

(5) The Administrator will be required to consider a submission for a health condition previously reviewed by the Administrator and found not to qualify for addition to the List of WTC-Related Health Conditions as a valid new petition only if the submission presents a new medical basis (*i.e.,* a basis not previously reviewed) for the association between the September 11, 2001, terrorist attacks and the condition to be added. A submission that provides no new medical basis and is received after the publication of a response in the **Federal Register** to a petition requesting the addition of the same health condition will not be considered a valid petition and will not be answered in a **Federal Register** notice pursuant to paragraph (a)(2), above. The interested party will be informed of the WTC Health Program's decision in writing.

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[37] Based on 2005–2009 average annual data age-adjusted to the 2000 U.S. population. *See* Glenn Copeland, Andrew Lake, Rick Firth, *et al.* (eds), *Cancer in North America: 2005–2009. Volume One: Combined Cancer Incidence for the United States, Canada and North America,* Springfield, IL: North American Association of Central Cancer Registries, Inc., June 2012.

(b) The Administrator may propose to add a condition to the List of WTC-Related Health Conditions in § 88.15 of this part by publishing a proposed rule in the **Federal Register** and providing interested parties a period of 30 calendar days to submit written comments. The Administrator may extend the comment period for good cause.

(1) If the Administrator requests a recommendation from the WTC Health Program Scientific/Technical Advisory Committee, the Advisory Committee will submit its recommendation to the Administrator no later than 90 calendar days after the date of the transmission of the request or no later than a date specified by the Administrator (but not more than 180 calendar days after the request). The Administrator will publish a proposed rule or a decision not to publish a proposed rule in the **Federal Register** no later than 90 calendar days after the date of transmission of the Advisory Committee recommendation.

(2) Before issuing a final rule to add a health condition to the List of WTC-Related Health Conditions, the Administrator will provide for an independent peer review of the scientific and technical evidence that would be the basis for issuing such final rule.

§ 88.17 Physician's determination of WTC-related health conditions.

(a) A physician affiliated with either a CCE or NPN will promptly transmit to the WTC Health Program a determination that a member's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks is substantially likely to be a significant factor in aggravating, contributing to, or causing the illness or health condition, including a mental health condition. The transmission will also include the basis for such determination. The physician's determination will be made based on an assessment of the following:

(1) The individual's exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks.

(2) The type of symptoms experienced by the individual and the temporal sequence of those symptoms.

(b) For a health condition medically associated with a WTC-related health condition, the physician's determination must contain information establishing how the health condition has resulted from treatment of a previously certified WTC-related health condition or how it has resulted from progression of the certified WTC-related health condition.

§ 88.18 Certification.

(a) *WTC-related health condition.* The WTC Health Program will review each physician determination and render a decision regarding certification of the condition as a WTC-related health condition. The WTC Health Program will notify the WTC Health Program member of the decision and the reason for the decision in writing.

(b) *Health condition medically associated with a WTC-related health condition.* The WTC Health Program will review each physician determination and render a decision regarding certification of the condition as a health condition medically associated with a WTC-related health condition. The WTC Health Program will notify the WTC Health Program member in writing of the decision and the reason for the decision within 60 calendar days after the date the physician's determination is received.

(1) In the course of review, the WTC Health Program may seek a recommendation about certification from a physician panel with appropriate expertise for the condition.

(2) [Reserved]

(c) *Appeal right.* If certification of a condition as a WTC-related health condition or a health condition medically associated with a WTC-related health condition is denied, the WTC Health Program member may appeal the WTC Health Program's decision to deny certification, as provided under § 88.21.

■ 10. Add § 88.19 to read as follows:

§ 88.19 Decertification.

(a) The decertification of a WTC Health Program member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition may be initiated by the WTC Health Program in the following circumstances:

(1) The WTC Health Program finds that the member's exposure is inadequate or is otherwise not covered;

(2) The WTC Health Program finds that the member's certified WTC-related health condition was certified in error or erroneously considered to have been aggravated, contributed to, or caused by exposure to airborne toxins, any other hazard, or any other adverse condition resulting from the September 11, 2001, terrorist attacks, pursuant to § 88.17(a); or

(3) The WTC Health Program finds that the member's health condition was erroneously determined to be medically associated with a WTC-related health condition, pursuant to § 88.17(b).

(b) A WTC Health Program member will be notified in writing by the WTC Health Program of a decertification decision, provided an explanation, as appropriate, for the decision, and provided information on how to appeal the decision. A WTC Health Program member whose WTC-related health condition or health condition medically associated with a WTC-related health condition is decertified may appeal the decertification decision in accordance with § 88.21 of this part.

■ 11. Add § 88.20 to read as follows:

§ 88.20 Authorization of treatment.

(a) *Generally.* Medically necessary treatment of certified WTC-related health conditions and certified health conditions medically associated with WTC-related health conditions will be provided through the CCEs or the NPN as permitted under WTC Health Program treatment protocols and in accordance with all applicable WTC Health Program policies and procedures.

(b) *Standard for determining medical necessity.* All treatment provided under the WTC Health Program will adhere to a standard which is reasonable and appropriate; based on scientific evidence, professional standards of care, expert opinion or any other relevant information; and which has been included in the medical treatment protocols developed by the Data Centers, with input from the CCEs, and approved by the Administrator of the WTC Health Program.

(c) *Treatment pending certification.* While certification of a condition is pending, authorization for treatment of a WTC-related health condition or a health condition medically associated with a WTC-related health condition must be obtained from the Administrator of the WTC Health Program before treatment is provided, except for the provision of treatment for a medical emergency.

■ 12. Add § 88.21 to read as follows:

§ 88.21 Appeal of certification, decertification, or treatment authorization decision.

(a) A WTC Health Program member or the member's designated representative (appointed pursuant to § 88.2(a)) may appeal the following four types of decisions made by the WTC Health Program:

(1) To deny certification of a health condition as a WTC-related health condition;

(2) To deny certification of a health condition as medically associated with a WTC-related health condition;

(3) To decertify a WTC-related health condition or a health condition medically associated with a WTC-related health condition; or

(4) To deny authorization of treatment for a certified health condition based on a finding that the treatment is not medically necessary.

(b) *Appeal request.* (1) A letter requesting an appeal must be postmarked within 90 calendar days of the date of the letter from the Administrator of the WTC Health Program notifying the member of the adverse decision. Electronic versions of a signed letter will be accepted if transmitted within 90 days of the date of the Administrator's notification letter.

(2) A valid request for an appeal must:

(i) Be made in writing and signed;

(ii) Identify the member and designated representative (if applicable);

(iii) Describe the decision being appealed and the reason(s) why the member or designated representative believes the decision is incorrect and should be reversed. The description may include, but is not limited to, the following: scientific or medical information correcting factual errors that may have been submitted to the WTC Health Program by the CCE or NPN; information demonstrating that the WTC Health Program did not correctly follow or apply relevant WTC Health Program policies or procedures; or any information demonstrating that the WTC Health Program's decision was not reasonable given the facts of the case. The basis provided in the appeal request must be sufficiently detailed and supported by information to permit a review of the appeal. Any new information not previously considered by the WTC Health Program must be included with the appeal request, unless later requested by the WTC Health Program; and

(iv) Be sent to the WTC Health Program at the address specified in the notice of denial.

(3) The appeal request may also state an intent to make a 15-minute oral statement by telephone. The WTC Health Program member or designated representative will have a second opportunity to schedule an oral statement after being contacted by the WTC Health Program regarding the appeal.

(c) *Appeal process.* Upon receipt of a valid appeal, the Administrator will appoint a Federal Official independent of the WTC Health Program to review the case. The Federal Official will review all available records relevant to the WTC Health Program's decision to deny certification of a health condition as a WTC-related health condition, deny certification of a health condition as medically associated with a WTC-related health condition, decertify the WTC-related health condition or health condition medically associated with a WTC-related health condition, or deny treatment authorization, and assess whether the appeal should be granted. The Federal Official's consideration will include the following: whether the WTC Health Program substantially complied with all relevant WTC Health Program policies and procedures; whether the information supporting the WTC Health Program's decision was factually accurate; and whether the WTC Health Program's decision was reasonable as applied to the facts of the case.

(1) In conducting his or her review, the Federal Official will review the case record, including any oral statement made by the WTC Health Program member or the member's designated representative, as well as additional relevant new information submitted with the appeal request or provided by the WTC Health Program member or the member's designated representative at the request of the WTC Health Program.

(2) The Federal Official may consult one or more qualified experts to review the WTC Health Program's decision and any additional information provided by the WTC Health Program member or the member's designated representative. The expert reviewer(s) will submit their findings to the Federal Official.

(3) The Federal Official will provide his or her recommendation regarding the disposition of the appeal, including his or her findings and any supporting materials (including the transcript of any oral statement and any expert reviewers' findings), to the Administrator.

(d) *Final decision and notification.* The Administrator will review the Federal Official's recommendation and any relevant information and make a final decision on the appeal. The Administrator will notify the WTC Health Program member and/or the member's designated representative of the following in writing:

(1) The recommendation and findings made by the Federal Official as a result of the review;

(2) The Administrator's final decision on the appeal;

(3) An explanation of the reason(s) for the Administrator's final decision on the appeal; and

(4) Any administrative actions taken by the WTC Health Program in response to the Administrator's final decision.

■ 13. Add § 88.22 to read as follows:

§ 88.22 Reimbursement for medical treatment and services.

(a) *Review of claims.* Each claim for reimbursement for treatment will be reviewed by the WTC Health Program. Claims that cannot be validated by that process will be further assessed by the Administrator of the WTC Health Program.

(b) *Initial health evaluations, medical monitoring, and medically necessary treatment.* (1) The costs incurred by a CCE or NPN-affiliated provider for providing a WTC Health Program member an initial health evaluation, medical monitoring, and/or medically necessary treatment or services for a WTC-related health condition or a health condition medically associated with a WTC-related health condition will be reimbursed according to the payment rates that apply to the provision of such treatment and services under the Federal Employees Compensation Act (FECA), 5 U.S.C. 8101 *et seq.*, 20 CFR part 10.

(i) The Administrator will reimburse a CCE or NPN-affiliated provider for treatment for which FECA rates have not been established pursuant to the applicable Medicare fee for service rate, as determined appropriate by the Administrator.

(ii) The Administrator will reimburse a CCE or NPN-affiliated provider for treatment for which neither FECA nor Medicare fee for service rates have been established, at rates as determined appropriate by the Administrator.

(2) If the treatment is determined not to be medically necessary or is inconsistent with WTC Health Program protocols, the Administrator will withhold reimbursement.

(c) *Outpatient prescription pharmaceuticals.* Payment for costs of medically necessary outpatient prescription pharmaceuticals for a WTC-related health condition or health condition medically associated with a WTC-related health condition will be reimbursed by the WTC Health Program under a contract with one or more pharmaceutical benefit management services.

■ 14. Add § 88.23 to read as follows:

§ 88.23 Appeal of reimbursement denial.

Appeal of reimbursement denial. After exhausting procedural and/or contractual administrative remedies, a CCE or NPN medical director or affiliated provider may submit a written appeal of a WTC Health Program decision to withhold reimbursement or payment for treatment found to be not medically necessary or not in accordance with approved WTC Health Program medical treatment protocols pursuant to § 88.20 of this part. Appeal procedures are published on the WTC Health Program Web site.

■ 15. Add § 88.24 to read as follows:

§ 88.24 Coordination of benefits and recoupment.

The WTC Health Program will attempt to recover the cost of payment for treatment, including pharmacy benefits, for a WTC Health Program member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition by coordinating benefits with any workers' compensation insurance available[38] for members' work-related health conditions, and with any public or private health insurance available[39] for members' non-work-related health conditions.

(a) Where a WTC Health Program member's WTC-related health condition or health condition medically associated with a WTC-related health condition is eligible for workers' compensation or another illness or injury benefit plan to which New York City is obligated to pay, the WTC Health Program is the primary payer.

(b) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition and the claim is pending, the WTC Health Program is the primary payer; however, if the claim is ultimately accepted by the workers' compensation board, the workers' compensation insurer in question is responsible for reimbursing the WTC Health Program for any treatment provided and/or paid for during the pendency of the claim.

(c) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition, but a final decision is issued denying the compensation for the claim, the WTC Health Program is the primary payer.

(d) Where a WTC Health Program member has filed a workers' compensation claim for a WTC-related health condition or health condition medically associated with a WTC-related health condition with a workers' compensation plan to which New York City is not obligated to pay, the workers' compensation insurer is the primary payer. The WTC Health Program is the secondary payer.

(1) If a WTC Health Program member settles a workers' compensation claim by entering into a settlement agreement that releases the employer or insurance carrier from paying for future medical care, the settlement must protect the interests of the WTC Health Program. This may include setting aside adequate funds to pay for future medical expenses, as required by the WTC Health Program, which would otherwise have been paid by workers' compensation. In such situations, the WTC Health Program may require reimbursement for treatment services of a WTC-related health condition or health condition medically associated with a WTC-related health condition directly from the member.

(2) The WTC Health Program will pay providers for treatment in accordance with § 88.22(b); to the extent that the workers' compensation insurance pays for treatment at a lower rate, the WTC Health Program will recoup treatments costs at the workers' compensation insurance rate.

(e) Where a WTC Health Program member's WTC-related health condition or health condition medically associated with a WTC-related health condition is not work-related, the WTC Health Program member's public or private health insurance plan is the primary payer. The WTC Health Program will pay costs not reimbursed by the public or private health insurance plan due to the application of deductibles, co-payments, co-insurance, other cost sharing arrangements, or payment caps up to and in accordance with the rates described in § 88.22(b).

(f) Any coordination of benefits or recoupment situation not described in paragraphs (a) through (e) of this section will be handled pursuant to WTC Health Program policies and procedures, as found on the WTC Health Program Web site.

■ 16. Add § 88.25 to read as follows:

§ 88.25 Reopening of WTC Health Program final decisions.

At any time, and without regard to whether new evidence or information is provided or obtained, the Administrator of the WTC Health Program may reopen any final decision made by the WTC Health Program pursuant to the provisions of this part. The Administrator may affirm, vacate, or modify such decision, or take any other action he or she deems appropriate.

Dated: July 27, 2016.

John Howard,

Administrator, World Trade Center Health Program and Director, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, Department of Health and Human Services.

Dated: July 27, 2016.

Sylvia M. Burwell,

Secretary, Department of Health and Human Services.

[FR Doc. 2016–18679 Filed 8–16–16; 8:45 am]

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[38] As described in PHS Act, sec. 3331(b). To the extent that payment for treatment of the member's work-related condition has been made, or can reasonably be expected to be made, under any other work-related injury or illness benefit plan of the member's employer, the WTC Health Program will also attempt to recover the costs associated with treatment, including pharmacy benefits, for the member's certified WTC-related health condition or health condition medically associated with a WTC-related health condition. *See* PHS Act, sec. 3331(b)(1). For purposes of this regulation, "workers' compensation law or plan" or "workers' compensation insurance" includes any other work-related injury or illness benefit plan of the WTC Health Program member's employer.

[39] As described in PHS Act, sec. 3331(c).

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